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☐ continuation patent application of
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☐ continuation-in-part patent application of

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Washington, D.C. 20231

By: Ron Anton

Inventor(s)/Applicant Identifier: ALBERT G. BURDULIS, JR. and KATHERINE WHITIN.

For: SYSTEMS, DEVICES AND METHODS FOR SUTURING PATIENT TISSUE

☐ This application claims priority from each of the following Application Nos./filing dates:

the disclosure(s) of which is (are) incorporated by reference.

☐ Please amend this application by adding the following before the first sentence: "This application is a ☐ continuation ☐ continuation-in-part of and claims the benefit of U.S. Provisional Application No. 60/_____, filed _____, the disclosure of which is incorporated by reference."

Enclosed are:

- ☒ 28 page(s) of specification
☒ 6 page(s) of claims
☒ 1 page of Abstract
☒ 28 sheet(s) of ☐ formal ☒ informal drawing(s).

An assignment of the invention to _____

A ☐ signed ☐ unsigned Declaration & Power of Attorney

A ☐ signed ☒ unsigned Declaration.

A Power of Attorney.

A verified statement to establish small entity status under 37 CFR 1.9 and 37 CFR 1.27 ☐ is enclosed ☐ was filed in the prior application and small entity status is still proper and desired.

A certified copy of a _____ application.

Information Disclosure Statement under 37 CFR 1.97.

A petition to extend time to respond in the parent application.

Notification of change of ☐ power of attorney ☐ correspondence address filed in prior application.

☒ title page

**In view of the Unsigned Declaration as filed with this application and pursuant to 37 CFR §1.53(f),
Applicant requests deferral of the filing fee until submission of the Missing Parts of Application.**

DO NOT CHARGE THE FILING FEE AT THIS TIME

Cornelius J. Wheeler

Granted Limited Recognition under 37 CFR § 10.9(b)
as set out in attached authorization.

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PATENT APPLICATION

**SYSTEMS, DEVICES AND METHODS
FOR SUTURING PATIENT TISSUE**

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SYSTEMS, DEVICES AND METHODS FOR SUTURING PATIENT TISSUE

CROSS-REFERENCES TO RELATED APPLICATIONS

5 This application is related to commonly assigned, copending U.S. Patent Application No. 08/824,031 filed on March 26, 1997, Patent Application No. 08/883,246 filed on June 26, 1997, Patent Application No. 08/638,076 filed on April 26, 1996, and Patent Application No. 09/395,901 entitled "Device and Method for Performing End-to-Site Anastomosis," filed on September 14, 1999. Furthermore, this application is related
10 to Patent Application No. 09/610,564 filed on June 30, 2000, Patent Application No. 09/610,099 filed on June 30, 2000 and Patent Application No. 09/608,832 filed on June 30, 2000. The full disclosure of each of the above applications is incorporated herein by reference.

FIELD OF THE INVENTION

15 This invention relates to suturing patient tissue together. In particular, the invention relates to a method of suturing patient tissue together, to a suture placement device and to a suture placement system.

BACKGROUND OF THE INVENTION

20 The invention can be used advantageously to suture vessels, ducts, and the like, in a patient body. The invention can be used particularly advantageously in suturing blood vessels together during cardiac surgery, for example. Accordingly, the invention can be used during coronary artery bypass graft surgery (CABG), and the like. However,
25 it is to be appreciated that the field of the invention is not to be limited to such uses only, but extends to suturing patient tissue together in general. For example, the invention can be used also to form sutures in bowel connections, femoral-popliteal artery anastomoses, and the like. It can also be used in the field of trauma closure, and the like.

30 It is often required to connect a vessel, duct, or the like, such as a hollow organ, or blood vessel, or the like, to a target piece of tissue, such as another vessel, duct, or the like. This is especially true in the case of certain types of cardiac surgery, such as CABG surgery. Often during such CABG surgery it is required to connect, or join, one blood vessel to another so that the vessels are joined together to be in fluid flow

communication with each other. A joint formed between blood vessels in this fashion is often referred to as an anastomosis.

As is well known, the heart pumps blood through the body. The heart comprises a plurality of muscles which cooperate with one another to cause contractions of the heart thereby to provide a pumping action. The heart requires blood flow to its muscles to provide its muscles with the necessary oxygen, nutrients, and the like, necessary for muscular contraction. It often happens that one or more of the blood vessels which feed the heart muscles becomes diseased and develops a blockage, or becomes occluded, or the like. When this happens, a region of the heart normally fed by that diseased blood vessel can experience a depletion, or interruption, of blood supply. If such a condition is not treated in a timely fashion, the patient may suffer a heart attack with often fatal results.

CABG procedures are often performed to circumvent such a blockage, or occlusion, in a diseased blood vessel, thereby to provide the region of the heart normally fed by the diseased vessel with blood. This procedure normally involves tapping blood from an appropriate blood source, such as a donor blood vessel such as, for example, the aorta, saphenous vein, mammary artery, or the like, and routing the tapped blood to the diseased vessel downstream of the occlusion or blockage. A variety of procedures are currently employed to provide tapped blood downstream of an occlusion, or blockage, in a diseased blood vessel. One procedure involves making use of a graft. In such a case, an end of the graft is typically sutured to an appropriate blood source to be in fluid flow communication therewith and an opposed end of the graft is typically sutured to a side of the diseased vessel to be in fluid flow communication therewith downstream of the occlusion, or blockage. Another procedure involves suturing a side of a healthy vessel to a side of a diseased vessel downstream of the blockage, or occlusion, so that blood can flow from the healthy vessel to the diseased vessel. A joint between an end of a vessel, or graft, and a side of another vessel, or graft, is often referred to as an end-to-side anastomosis. A joint between a side of a graft, or vessel, and a side of another graft, or vessel, is often referred to as a side-to-side anastomosis.

During CABG surgery, a patient is often connected to a cardiopulmonary bypass machine so that the heart can be stopped temporarily, thereby to ease the task of suturing the various grafts, and/or vessels, together. Furthermore, blood vessels, such as the aorta, for example, are often closed, or clamped, so as to interrupt blood flow through that vessel when that vessel is to be used as a donor vessel or blood source.

When CABG procedures are performed on a patient, the patient normally suffers a great deal of trauma. Accordingly, it would be beneficial if such CABG procedures could be improved so as to decrease patient trauma. In conventional CABG surgery, there are at least three factors that affect the degree of trauma suffered by a patient. These factors include: (1) the time the patient spends on a cardiopulmonary bypass machine, (2) the time the patient spends with a clamped blood vessel, such as the aorta, or the like, and (3) the quality of the anastomoses formed between the blood vessels and/or grafts. It is generally recognized that the risk of patient morbidity rises significantly after the patient has been placed on a cardiopulmonary bypass machine for a period of about one hour. Passage of blood through a cardiopulmonary bypass machine tends to damage blood cells consequently causing degradation in blood quality.

Accordingly, the longer a patient is subjected to cardiopulmonary bypass, the more the blood cells become damaged and the higher the degradation in the quality of the blood. A complication often associated with prolonged placement on a cardiopulmonary bypass machine, is distal thrombosis. Distal thrombosis can give rise to embolization in the neurovasculature and can lead to the patient suffering a stroke. Accordingly, it would be beneficial if the period a patient spends on a cardiopulmonary bypass machine during CABG surgery could be reduced.

A factor by which the amount of time a patient spends on a cardiopulmonary bypass machine can be reduced is by reducing the time taken suturing the vessels and/or grafts together to form anastomoses. The average time taken to suture two vessels together to form an anastomosis in accordance with traditional suturing methods, is typically about seven to ten minutes. An average CABG procedure can involve the formation of about five anastomoses. Accordingly, the time spent on suturing during an average CABG procedure can be between about thirty-five to fifty minutes. Therefore, since the task of suturing can constitute a major portion of the one hour period, it would be advantageous if the time spent on such suturing could be reduced. By doing so, the time a patient is subjected to cardiopulmonary bypass would also be reduced, thereby reducing patient trauma and the risks of morbidity.

In so-called "off-pump" procedures, patients are not placed on cardiopulmonary bypass machines. Accordingly, the negative effects associated with cardiopulmonary bypass mentioned above are inhibited. However, the task of suturing is made more difficult since the task of suturing is normally then performed while the heart is beating. This can lead to the formation of anastomoses with reduced integrity.

Improperly suturing blood vessels and/or grafts together may lead to post operative complications. Incorrect suturing during surgery requiring correction during the surgery, may unnecessarily extend the time taken to complete the surgery.

Suture placement devices have been proposed which enable a surgeon, or the like, to place suture elements in patient tissue without manually holding and manipulating a suture needle, as has traditionally been the case. It has been found that the management of opposed ends of suture elements after having been placed in patient tissue with such a device can be rather tedious. This is especially true where the device is arranged to place a plurality of suture elements in patient tissue simultaneously. In such a case, opposed portions of each individual suture element are typically secured together to form a suture. It has been found that the opposed portions can become mixed up, or entangled, with one another, thereby unnecessarily complicating the suturing procedure and delaying its completion.

Accordingly, it would be advantageous to provide systems, devices and methods for enabling suturing operations to be conducted with greater accuracy and in a shorter period of time. This is especially true if several vessels and/or grafts are to be sutured together during a CABG procedure.

SUMMARY OF THE INVENTION

According to one aspect of the invention, there is provided a method of suturing patient tissue together. The method comprises positioning a suture placement device adjacent patient tissue, the suture placement device having a body and a suture holder releasably attached on the body. The method further comprises actuating the suture placement device and causing the suture placement device to pass an end portion of at least one suture element through the patient tissue in response to actuating the suture placement device. The method further comprises causing the end portion of the at least one suture element to be held on the suture holder of the device after the end portion has been passed through the patient tissue and detaching the suture holder from the body of the device while the end portion of the at least one suture element is held thereon.

By holding the suture element on such a suture holder, and detaching the holder from the device while the end portion of the at least one suture element is held thereon, management of the suture portion is made relatively easy since the holder can be formed to be readily manipulatable by a user's hand, as opposed to manipulating the end portion of the suture element directly.

According to another aspect of the invention, there is provided a suture placement device. The suture placement device comprises a body, a support on the body, the support being arranged releasably to hold an end of at least one suture element and at least one engaging element displaceably mounted on the body. The engaging element is arranged to pass through patient tissue so as to engage the end of the at least one suture element when held on the support and to withdraw from the tissue while the end of the suture element is engaged therewith, thereby to pass the end of the suture element through the tissue. The device further comprises a suture holder on the body. The suture holder is arranged to hold the end of the at least one suture element after it has been passed through the tissue. The suture holder is releasably attached to the body so that the end of the at least one suture element can be removed from the body by detaching the suture holder from the body while the end of the at least one suture element is held thereon.

According to yet a further aspect of the invention, there is provided a suture placement system. The system comprises at least two suture placement devices. Each device comprises a body, a support on the body, the support being arranged releasably to hold an end of at least one suture element and at least one engaging element displaceably mounted on the body. The engaging element is arranged to pass through patient tissue so as to engage the end of the at least one suture element when held on the support and to withdraw from the tissue while the end of the suture element is engaged therewith, thereby to pass the end of the suture element through the tissue. The device further comprises a suture holder on the body. The suture holder is arranged to hold the end of the at least one suture element after it has been passed through the tissue. The suture holder is releasably attached to the body so that the end of the at least one suture element can be removed from the body by detaching the suture holder from the body while the end of the at least one suture element is held thereon.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described, by way of example, with reference to the accompanying diagrammatic drawings, in which:

Figure 1A shows a schematic side view of a patient's heart;

Figure 1B shows a schematic cross sectional side view of an end-to-side anastomosis between two vessels;

Figure 1C shows a schematic cross sectional side view of a side-to-side anastomosis between two vessels;

Figure 2A shows a schematic side view of a suture placement system in accordance with the invention, the suture placement system comprising two suture placement devices in accordance with the invention, the system being arranged to form a side-to-side anastomosis;

5 Figure 2B shows a schematic cross-sectional view of a flexible member of the system shown in Figure 2A along arrows II-II in Figure 2A;

Figure 3 shows, at an enlarged scale, a schematic three-dimensional view of part of one of the suture placement devices of the system shown in Figure 2A;

10 Figure 4 shows a schematic three-dimensional exploded view corresponding to Figure 3;

Figure 5 shows a schematic three-dimensional view of part of a suture holder of the suture placement device shown in Figure 3;

Figure 6 shows a schematic three-dimensional view of a suture support of the suture placement device shown in Figures 3;

15 Figure 7A shows, at an enlarged scale, a schematic three-dimensional view of part of the suture support shown in Figure 6;

Figure 7B shows a schematic three-dimensional view of an end of a suture element secured to a cuff;

20 Figure 7C shows a schematic side view of part of the suture support of Figure 7A indicating how the cuff of Figure 7B is received in a seat defined by the part of the suture support shown in Figure 7A;

Figures 8A to 8E show schematic side views of one of the suture placement devices in accordance with the invention and illustrates sequential steps indicating the operation of the suture placement device;

25 Figure 9 shows a schematic three-dimensional view of the suture support of one of the devices of the system shown in Figure 2A, the support being operatively positioned to extend through an aperture in a side of a blood vessel;

30 Figure 10 shows a schematic three-dimensional view corresponding to Figure 9, and shows engaging elements of the suture placement device after the engaging elements have engaged ends of a plurality of suture elements and have drawn the ends through a wall of the vessel adjacent the aperture to place the sutures in the vessel wall;

Figure 11 shows a schematic end view along arrow III in Figure 10 and shows the suture support being removed from the vessel through the aperture after the suture elements have been placed in the vessel wall adjacent the aperture;

Figure 12 shows a schematic three-dimensional view corresponding to Figures 9 and 10, and shows the suture support having been withdrawn from the vessel through the aperture after the suture elements have been placed in the vessel wall;

Figure 13 shows a schematic view of one of the suture placement devices being supported at a position remote from a vessel on which a plurality of suture elements have been placed using the device;

Figure 14 shows a schematic three-dimensional view of the suture holders of both suture placement devices of the system shown in Figure 2A, after the one device has been used to place suture elements in a wall of a target vessel adjacent an aperture in the target vessel and the other device has been used to place the suture elements through a wall of a donor vessel adjacent an aperture in the donor vessel;

Figure 15 shows a three-dimensional schematic view corresponding to Figure 14, one part of the suture holder of the one device having been paired with one part of the suture holder of the other device thereby to bring opposed end portions of the same suture elements together;

Figure 15A shows a schematic cross-sectional view corresponding to Figure 14;

Figure 16 shows a schematic three-dimensional view showing a suture-handling device being passed across paired end portions of the suture elements after the opposed end portions have been paired up;

Figure 17 shows a schematic three-dimensional view corresponding to Figure 16, the suture-handling device having been passed across the paired end portions of the same suture elements, each pair of opposed portions of the suture element having been received in a slot of the suture-handling device;

Figure 18 shows a schematic three-dimensional view corresponding to Figure 17 and shows the vessel walls of the target and donor vessels having been drawn together and the suture elements having been pulled through the vessel walls;

Figure 19 shows a schematic side view of another suture placement system in accordance with the invention, the suture placement system comprising two suture placement devices arranged to form an end-to-side anastomosis;

Figure 20 shows a schematic three-dimensional view of one of the suture placement devices of the system shown in Figure 19, the device being arranged to place suture elements through a vessel wall at an end of a vessel adjacent a mouth of the vessel;

Figure 21 shows, at an enlarged scale, part of the device shown in Figure 20, a suture holder retainer of the suture placement device being shown in an open condition;

Figure 22 shows, at an enlarged scale, a schematic part sectional side view of part of a vessel support shaft of the suture placement device, a needle of the suture placement device being shown in a dormant position within a passage defined in the shaft;

Figure 23 shows a schematic part sectional side view corresponding to Figure 22, the needle of the suture placement device having been displaced from its dormant position to an extended position;

Figure 24 shows a schematic three-dimensional view corresponding to Figure 20, a suture holder retainer of the suture placement device being shown in an open condition and further showing a plurality of suture elements, end portions of which are attached to ends of needles;

Figure 25 shows a schematic three-dimensional view corresponding to Figure 24, and shows an end portion of a vessel or graft received on the vessel support shaft of the suture placement device;

Figure 26 shows a schematic three-dimensional view corresponding to Figure 25 and shows the suture holder retainer in a closed condition after the end portion of the vessel or graft has been positioned on the vessel support shaft;

Figure 27 shows a schematic three-dimensional view corresponding to Figure 26, the suture holder retainer being shown in an open condition and further showing the needles having been passed through the vessel or graft adjacent a mouth of the vessel or graft supported on the vessel support shaft;

Figure 28 shows a schematic three-dimensional view of the end portion of the graft, after the needles of the suture placement device have been passed through the graft adjacent its mouth, the needles being held on suture holders of the suture placement device, the suture holders having been removed from the suture holder retainers of the suture placement device;

Figure 28A shows a schematic three-dimensional view of one of the suture holders normally retained on an associated suture holder retainer of the device, the suture holder being shown having a shape corresponding to its shape when retained on its associated suture holder retainer; and

Figure 28B shows a schematic three-dimensional view of the suture holder of Figure 28A having a shape corresponding to its shape when in a relaxed condition after having been removed from its associated suture holder retainer.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Referring to Fig. 1A of the drawings, a patient's heart is generally indicated by reference numeral 10. The heart 10 is shown after a CABG procedure has been performed thereon. The CABG procedure involved suturing an end 12.1 of a graft 12 to the aorta 14 and an opposed end 12.2 of the graft 12 to a target vessel 16 downstream of a blockage, or occlusion 18, in the target vessel 16. After completion of the CABG procedure, blood is supplied to a region of the heart downstream of the occlusion 18, which region was subjected to a depletion, or starvation, of blood, because of the occlusion 18 in the vessel 16.

During the CABG procedure, an incision was made in the aorta 14 and the vessel 16 respectively. The graft 12 was sutured to the aorta 14 and the vessel 16 such that open mouths at the ends 12.1, 12.2 of the graft 12 are connected to the aorta 14 and vessel 16 respectively so that blood can flow through the incision in the aorta 14, through the mouth of the graft 12 at its end 12.1, internally along the graft 12, through its mouth at its end 12.2 and through the incision in the target vessel 16, and then along the vessel 16 downstream of the occlusion 18. In this way, blood is tapped from the aorta 14 and supplied to the region of the heart normally supplied by the vessel 16, if not for the occlusion 18. When the ends 12.1, 12.2 were joined to the aorta 14 and vessel 16 respectively, anastomoses were thus formed at 22, 24 respectively. The graft 12 was joined to the aorta 14 and vessel 16 by means of sutures 26 to form the anastomoses 22, 24.

The anastomoses at 22, 24 are examples of what is often termed end-to-side anastomoses. The end-to-side anastomosis at 22 is shown schematically, and in greater detail, in Figure 1B of the drawings, in which like reference numerals have been used to designate similar parts or features, unless otherwise stated. A CABG procedure can involve forming one or more side-to-side anastomoses. An example of such a side-to-side anastomosis is indicated generally by reference numeral 20 in Figure 1C of the drawings. The side-to-side anastomosis 20 extends between a side 21.1 of a vessel 21 and an opposed side 23.1 of another vessel 23. By means of such a side-to-side anastomosis 20, blood can flow from one of the vessels 21, 23 to the other of the vessels

21, 23. In this way, blood can be tapped from one of the vessels 21, 23 to the other of the vessels 21, 23 at a position downstream of a blockage, or occlusion, in the other of the vessels 21, 23.

A suture placement system, in accordance with the invention, which can be used advantageously to form a side-to-side anastomosis as indicated in Figure 1C, will now be described with reference to Figures 2A and 2B of the drawings.

Referring to Figure 2A, the suture placement system for forming a side-to-side anastomosis is generally indicated by reference numeral 110. The system 110 includes two suture placement devices generally indicated by reference numerals 112, 114 respectively. Each device 112, 114 comprises a body 115 and a suture holder, generally indicated by reference numeral 116. In the embodiment of the invention shown in Figure 2A, each holder 116 comprises two parts 116.1, 116.2. Each of the bodies 115 further comprises a suture support, generally indicated by reference numeral 118.

The devices 112, 114 are connected together by an elongate flexible member 120. The member 120 can be formed of any appropriate flexible material, such as a synthetic plastics material, or the like. The material of which the member 120 is made is preferably bio-compatible. The member 120 defines two conduit portions 121.1, 121.2 extending longitudinally in series along one side 122 of the member 120. The member 120 further defines a suture container portion 121.3 for containing portions of a plurality of suture elements extending between the devices 112, 114, as will be described in greater detail below. The suture container portion 121.3 extends longitudinally along an opposed side 124 of the member 120. The member 120 further defines a longitudinally extending web 126 that connects the two conduit portions 121.1, 121.2 on the side 122 of the member 120 to the suture container portion 121.3 on the opposed side 124 of the member 120.

The system 110 comprises another elongate flexible member generally indicated at 130. The member 130 can typically be formed of a material which is the same as the material of which the member 120 is made. Accordingly, it can be formed from a synthetic plastics material and is preferably bio-compatible. The member 130 defines two conduit portions 131.1, 131.2 extending longitudinally along opposed sides 132, 134 thereof. The conduit portions 131.1, 131.2 are connected together by means of a longitudinally extending web 136 extending along and between the conduit portions 131.1, 131.2 for a portion of their lengths. The web 136 connecting the conduit portions 131.1, 131.2 together ends at 138. From the end of the web 136 at 138, the conduit

portions 131.1, 131.2 are free of each other. Each conduit portion 131.1, 131.2 carries a female Luer-type connector 140 at a free end 142 thereof. The female Luer-type connectors 140, 140 are arranged to be releasably connectable to complementary male Luer-type connectors on syringes (not shown).

5 The member 130 is connected to the member 120 at 143 such that ends 144, 144 of the conduit portions 131.1, 131.2 are connected to the conduit portions 121.1, 121.2 respectively, to be in fluid flow communication therewith. To this end, the ends 144, 144 are provided with laterally outwardly protruding formations 128 which extend into the conduit portions 121.1, 121.2 respectively. Advantageously, the formations 128, 128 are received in the conduit portions 121.1, 121.2 to permit angular displacement of the member 130 relative to the member 120 as indicated by arrows A. A fluid flow passage indicated in dashed lines by reference numeral 146 extends from one of the female Luer-type connectors 140, along the conduit portions 131.1, 121.1, to the device 112. Another fluid flow passage indicated in dashed lines by reference numeral 148 extends from the other of the female Luer-type connector 140, along the conduit portions 131.2, 121.2, to the device 114.

15 The body 115 of each device 112, 114 includes a cylinder 150 defining an internal chamber 152. The conduit portions 121.1, 121.2 are connected in fluid flow communication with the internal chambers 152, 152 through ports 153, 153. A piston 155 is received in the cylinders 150, 150 of each device 112, 114. The body 115 of each device 112, 114 comprises a shaft 154 on which its associated piston is mounted. The shafts 154, 154 are selectively extendable and retractable relative to the cylinders 150, 150 as indicated by arrows B, in response to pressurizing and de-pressurizing the chambers 152, 152. Pressure relief valves 151, 151 are provided in the conduit portions 131.1, 131.2 so as to inhibit the chambers 152, 152 from being pressurized beyond a predetermined pressure, as will be described in greater detail herein below.

20 The system 110 further comprises a plurality of suture elements. In Figure 2A, one of the suture elements is indicated schematically in dashed lines by reference numeral 160. Each of the suture elements defines opposed ends at 160.1, 160.2 respectively. The end 160.1 of each of the suture elements 160 is supported on the suture support 118 of the device 112 and the opposed end 160.2 of each suture element 160 is supported on the suture support 118 of the other device 114. The suture elements 160 extend from the suture support 118 of the device 112, snugly adjacent an outer surface of the cylinder 150 of the device 112 and into a lumen 121.4 defined within the suture

container portion 121.3 of the member 120. The suture elements then extend longitudinally along the lumen 121.4, out from the lumen 121.4 at the device 114, and then snugly adjacent an outer surface of the cylinder 150 of the other device 114 to the support 118 of the other device 114.

5 As can best be seen with reference to Figure 2B of the drawings, in which like reference numerals have been used to designate similar parts and features unless otherwise stated, the portion 121.3 defines a longitudinally extending slit 121.5 through which the suture elements 160 can be drawn from the longitudinally extending lumen 121.4. The portion 121.3 defines opposed longitudinally extending flange portions 121.6, 121.7 between which the slit 121.5 is defined. Longitudinally extending free edges of the flange portions 121.6, 121.7 are resiliently urged toward each other thereby resiliently to keep the slit 121.5 in a closed condition so as to contain, or hold, the portions of the suture elements extending along the lumen 121.4 within the lumen 121.4. When the suture elements 160 are drawn from the portion 121.3, the free edges of the flange portions 121.6, 121.7 part readily to permit the suture elements to be drawn from the lumen 121.4 with little effort.

10 Referring now to Figures 3 to 7 of the drawings, certain parts of the devices 112, 114 will now be described in greater detail. The suture support 118 of each device 112, 114 comprises a foot portion 118.1 and a shaft portion 118.2. The foot portion 118.1 is attached to an end of the shaft portion 118.2. As can best be seen in Figure 6, an opposed end of the shaft portion 118.2 has a hole 118.3 extending therethrough. The suture support 118 is secured relative to the cylinder 150 by means of a connecting pin (not shown) extending through the hole 118.3. The connecting pin is typically secured on the body 115. As can best be seen in Figure 4 of the drawings, the shaft 154 has a longitudinally extending slot 154.1. When the shaft 154 is selectively extended and retracted relative to its associated cylinder 150 in response to pressurizing and de-pressurizing the associated chamber 152, the connecting pin securing the suture holder 118 on the body 115 rides in the slot 154.1 so as not to interfere with displacement of the shaft 154.

25 As mentioned, the suture holder 116 of each device 112, 114 has two parts 116.1, 116.2. Each part 116.1, 116.2 is releasably held on the shaft of its associated body 115. To this end, each part 116.1, 116.2 has a catch formation 116.3 for resiliently engaging in a complementary slot, or recess, 154.2 on the shaft 154. As can best be seen in Figure 3 of the drawings, the parts 116.1, 116.2 are disengagable from the shaft 154 by

causing them to bend resiliently so that the catch formations 116.3, 116.3 disengage from the recesses 154.2, as indicated by arrows C. The parts 116.1, 116.2 of the suture holders 116 can be formed from any appropriate material such as a resilient synthetic plastics material, or the like. Preferably, the parts 116.1, 116.2 are of a bio-compatible material.

5 Typically, when the catch formations 116.3, 116.3 are caused to disengage from the shaft 154, the parts 116.1, 116.2 bend resiliently in the regions indicated at 116.5.

Conveniently, the parts 116.1, 116.2 have laterally outwardly protruding portions, generally indicated by reference numerals 116.6, 116.6, to enable the parts to be manipulated between a thumb and index finger, for example, of a user's hand. The parts 10 116.1, 116.2 further comprise inclined surfaces 116.4, 116.4. The surfaces 116.4, 116.4 are arranged to cooperate with the body 115 so that when the shaft 154 is retracted into its associated cylinder 150 by an amount exceeding a predetermined amount, the inclined surfaces 116.4 ride against the body 115 so as to urge the catch formations 116.3 from the recesses 154.2 thereby to cause the parts 116.1, 116.2 to disengage from the shaft 154 15 automatically, as will be described in greater detail herein below.

The parts 116.1, 116.2 of the suture support 116 further comprise a plurality of engaging elements for engaging the ends 160.1, 160.2 of the suture elements 160 on the suture supports 118, 118. The engaging elements can be of any appropriate form so as to cooperate with the ends 160.1, 160.2 of the suture elements 160 so as to 20 enable the ends 160.1, 160.2 of the suture elements 160 to be engaged by the engaging elements. Conveniently, the engaging elements are in the form of needles 170 and are arranged to engage cuffs to which the ends of the suture elements are secured, as will be described in greater detail below. It will be appreciated that any appropriate engaging arrangement between the suture element ends and the engaging elements can be used 25 instead of needles and cuffs. For example, use can be made of hook and loop arrangements, lasso-like arrangements, or the like.

As can best be seen in Figures 4 and 5 of the drawings, the needles 170 are secured in holes, or apertures, 172 extending through the parts 116.1, 116.2. The needles 170 are arranged to engage with the ends 160.1, 160.2 of the suture elements 160 held on 30 the suture supports 118, 118. As can best be seen with reference to Figures 7A to 7C of the drawings, the foot portion 118.1 of the suture holder 118 comprises a plurality of seats 118.4. Each seat 118.4 defines a cross-sectionally part circular hole 118.5 defining a laterally extending slit 118.7. A circumferentially intruding collar formation 118.6 is provided at the base of each hole 118.5. As can best be seen with reference to Figure 7B,

the end 160.1, 160.2 of each suture element 160 is secured to a cuff 117 whereby the end of the suture element is held on the support 118. Each cuff 117 comprises a cylindrical member 117.1 having an axially extending hole 117.2. Conveniently, the end 160.1, 160.2 of each suture element 160 is secured to an associated cuff 117 by inserting the end into the hole 117.2 at one end of the cuff 117 and securing the end 160.1, 160.2 of the suture element 160 to the cuff 117. Naturally, the end of the suture element 160 can be secured to the cuff 117 in any appropriate manner, such as, by using an appropriate adhesive, by means of soldering or welding, by means of an interference fit, by means of crimping, or the like. Instead, the cuffs can be formed integrally on the ends of the suture elements 160.

The ends 160.1, 160.2 of the suture elements 160 are releasably held on the foot 118.1 of the suture support 118 by means of the cuffs 117 being seated in the seats 118.4. When the needles 170 of the holders 116 are advanced relative to the body 115 in response to the shaft 154 being extended, the needles follow paths that are in register with the holes 117.2 in the cuffs 117 when the cuffs are seated in the seats 118.4. The needles 170 have pointed ends 170.1 arranged to pass into the holes 117.2 so as to engage with the cuffs 117. The lateral dimensions of the needles 170 at their pointed ends 170.1 and an internal diameter of the holes 117.2 are arranged to cooperate such that when the ends 170.1 of the needles 170 are advanced into the holes 117.2, the cuffs 117 are deformed radially outwardly so as to be frictionally engaged on the pointed ends 170.1 of the needles 170. After such engagement, the needles 170 can be withdrawn from the foot portion 118.1 in sympathy with retraction of the shaft 154 in response to retraction of the piston 155 in the cylinder 150. As the needles 170 are withdrawn in this fashion, the cuffs 117, and consequently also the ends 160.1, 160.2 of the suture elements 160 secured to the cuffs 117, are withdrawn from the seats 118.4.

Referring now to Figures 8A to 8E of the drawings, the operation of one of the devices 112, 114 will now be described in greater detail. In Figures 8A to 8E, the same reference numerals have been used to designate similar parts and features unless otherwise stated. For the sake of convenience, operation of the device 112 will be described. It will be appreciated that the device 114 operates in a manner similar to that of the operation of the device 112.

To operate the device 112, a syringe (not shown) is operatively connected to the female Luer-type connector 140 connected in fluid flow communication with the internal chamber 152 of the device 112, as can best be seen with reference to Figure 2A.

A plunger of the syringe is then depressed to cause an appropriate fluid, such as air, a saline solution, or the like, to flow along the fluid flow passage 146 in fluid flow communication with the chamber 152 of the device 112. In this way, the chamber 152 is pressurized so as to cause the piston 155 to advance within the cylinder 150, as indicated by arrow D in Figure 8A. In consequence, the shaft 154 is caused to advance in sympathy with advancement of the piston 155. Since the suture holder 116 is engaged on the shaft 154, it is caused to advance also. As the suture holder 116 advances, the needles 170 of the parts 116.1, 116.2 of the holder 116, advance toward the cuffs 117 on the foot 118.1 of the suture support 118. Eventually, as can best be seen in Figure 8B, the pointed ends 170.1 of the needles 170 are urged into the holes 117.2 of the cuffs 117 so as to cause the cuffs to be engaged on the ends 170.1 of the needles 170. Accordingly, since the ends 160.1 of the suture elements 160 are secured to the cuffs 117, the ends 160.1 are then also engaged with the needles 170.

With reference to Figure 2A, the relief valve 151 operatively connected in the fluid flow passage 146 is provided to inhibit the needles 170 from being advanced too far. The pressure relief valve 151 is typically arranged so as to relieve pressure in the fluid flow passages 146 at a pre-determined pressure corresponding to when the needles 170 have engaged with the cuffs 117. It will be appreciated that resistance to advancement of the needles 170 into the holes 117.2 of the cuffs 117 increases after the cuffs 117 have been engaged. In consequence, when the cuffs 117 have been engaged, an increase in pressure is required in the chamber 152 to cause the needles 170 to advance further. By providing the pressure relief valve 151 in the fluid flow passage 146 so as to relieve pressure when the pressure increases beyond the pressure needed to cause the needles 170 to engage the cuffs, over extension of the needles 170 is inhibited. When the predetermined pressure in the fluid flow passage 146 is reached, the fluid in the fluid flow passage expels from the passage 146 through the valve 151. The valve 151 is conveniently placed so that the expulsion of the fluid from the passage 146 is readily detectable by a user of the system 110, thereby to serve as a signal to the user that the cuffs 117 have been engaged and that depression of the plunger of the syringe can now stop.

In Figure 8B, the needles 170 are shown in a condition in which the cuffs 117 on the foot portion 118.1 have been engaged. The plunger of the syringe can then be withdrawn into its cylinder thereby to cause the chamber 152 of the device 112 to depressurize so as to cause the piston 155 to retract into the cylinder 150. As the piston

155 retracts in this fashion, the needles 170 are withdrawn from the foot portion 118.1 of the suture holder 118. As can best be seen with reference to Figure 8C, as the needles 170 withdraw, the ends 160.1 of the suture elements 160, now engaged on the needles 170 by means of the cuffs 117, are withdrawn from the foot 118.1.

5 As can further be seen with reference to Figure 8C, as the shaft 154 is caused to retract further, a stage is reached when the inclined surfaces 116.4, 116.4 of the parts 116.1, 116.2 of the holder 116 make contact with the body 115 of the device 112. The part of the body 115 with which the inclined surfaces 116.4 make contact, is indicated by reference numeral 115.1 in Figures 8A to 8E. As the shaft 154 is caused to
10 retract further, the inclined surfaces 116.4 ride along an outer peripheral edge of the part 115.1. In consequence, the portion 116.6 of each part 116.1, 116.2 of the holder 116 are urged laterally away from the body 115 thereby causing the portions 116.5 to bend resiliently and the catch formations 116.3, 116.3 to disengage from the recesses 154.2 on the shaft 154. In this manner, the parts 116.1, 116.2 become disengaged from the shaft
15 154 and therefore also from the body 115 of the device 112, as can best be seen in Figure 8D.

As can best be seen with reference to Figures 4 and 5 of the drawings, the parts 116.1, 116.2 of the holder 116 have channel formations 116.7. The channel
20 formations 116.7 together define a passage through which the shaft portion 118.2 of the suture support 118 extends when the parts 116.1, 116.2 are mounted on the body 115 of the device 112. The channel formations 116.7 are arranged to embrace the shaft 118.2 so that when the catch formations 116.3, 116.3 of the parts 116.1, 116.2 are disengaged from the shaft 154 of the body 115 of the device 112, the parts 116.1, 116.2 are frictionally
25 held on the shaft 118.2 by virtue of the shaft 118.2 being embraced by the parts 116.1, 116.2 in the channels 116.7, 116.7. Accordingly, as shown in Figure 8D, the parts 116.1, 116.2 are retained on the shaft portion 118.2 after the catch formations 116.3 have disengaged from the recesses 154.2 of the shaft 154.

As can best be seen in Figure 8E, after disengagement of the parts 116.1, 116.2 from the shaft 154, the portions 116.6, 116.6 of each part 116.1, 116.2 of the holder
30 116 can then be gripped between a thumb and finger of a user, for example, so that the parts 116.1, 116.2 can be removed manually from the body 115 of the device 112, as indicated by arrows G.

The system 110 will now be described in use and with reference to Figures 9 to 18 of the drawings. The system 110 will be described, by way of example, with

reference to forming a side-to-side anastomosis between two blood vessels during a CABG procedure.

Referring initially to Figure 9 of the drawings, to form such a side-to-side anastomosis between two vessels, an incision, or cut, 180 is made in a target vessel 182.

Typically, the target vessel 182 can have an occlusion, or the like, upstream of the incision 180, which occlusion interrupts, or reduces, blood flow to a region of the heart downstream of the occlusion. To form a side-to side anastomosis, a spacing pattern of the ends 116.1 on the support 118 of the device 112, generally indicated by reference numeral 184 in Figure 9A of the drawings, is generally the same for both devices 112, 114. The spacing pattern 184 of the ends 116.1 of the suture elements on the foot portion 118.1 of the device 112 can best be seen with reference to Figure 9A of the drawings.

Accordingly, the devices 112, 114 can typically be used interchangeably to place suture in either the target vessel 182 or a donor vessel, from which blood is to be tapped to the target vessel, as will be described in greater detail herein below. In the discussion which follows, by way of example, the device 112 will be used to place suture in the target vessel 182 and the device 114 will be used to place suture in the donor vessel.

The incision 180 should preferably be of a length which corresponds to the spacing pattern 184 of the suture ends on the foot portion 118.1, so that when a side-to-side anastomosis has been formed between the vessels by the system 110, the anastomosis will have a high degree of integrity. It will be appreciated that, should the incision 180 be formed to have too great a length, leakage of blood could ensue after the anastomosis has been formed. Should the incision 180 have too short a length, blood flow through the anastomosis can be impeded unnecessarily. Therefore, it would be advantageous if the incision 180 could be formed to have a specific predetermined length, which corresponds to the spacing pattern of the suture ends 116.1 on the support 118 of the device 112. It would further be advantageous if such an incision 180 could be formed accurately, repeatedly, and with little effort. To form the incision 180 such that it has a length which corresponds to the spacing pattern of the suture ends 116.1 on the support 118, use can be made of a surgical scissors arranged to form a cut, or aperture, of predetermined length. Such a scissors is disclosed in Applicant's co-pending Patent Application No. 09/610,564, filed June 30, 2000, entitled "Scissors", the full disclosure of which is incorporated herein by reference.

After the incision 180 has been made in the target vessel 182, the suture support 118 of the device 112 is passed through the incision 180 such that the foot portion

170 to withdraw from the foot portion 118.1 while the cuffs 117 are engaged on the ends 170.1 of the needles 170 thereby to pass the ends 160.1 of the suture elements through the vessel wall adjacent the incision 180. The plunger of the syringe is typically withdrawn until the parts 116.1, 116.2 are disengaged from the shaft 154 so that they are held

frictionally on the shaft portion 118.2 as shown in Figure 8E and as described above.

After the ends 160.1 of the suture elements 160 have been passed through the vessel wall 182.1 in this fashion, the foot portion 118.1 is removed from the target vessel 182 through the incision 180. To do this, and as can best be understood with reference to Figures 7A to 7C and Figure 11 of the drawings, the suture elements 160 are displaced laterally from the seats 118.4 of the foot portion 118.1 and through the slits 118.7, so as to be free of the foot portion 118.1. Typically, the suture elements 160 extend from the seats 118.4 operatively below the foot portion 118.1 and up along a side of the shaft portion 118.2 which is positioned adjacent the heel portion 118.9 of the foot portion 118.1. The suture elements are typically made from a material having a degree of resilience. Accordingly, the suture elements typically flex in a lateral direction so as to pass naturally from the seats 118.4 through the slits 118.7 when the cuffs 117 are withdrawn from the seats 118.4. Instead, or in addition, and as can best be seen in Figure 11 of the drawings, the suture elements can be caused to pass through the slits 118.7 by gently rocking the foot portion 118.1 in a sideways direction as indicated by arrows H-H. When the foot portion 118.1 is rocked gently in this fashion, the suture elements 160 can be passed through the slits 118.7 so as to be free of the foot portion 118.1. After the suture elements have been freed from the foot portion 118.1, the foot portion 118.1 is removed from the vessel 182 through the incision 180, as can best be seen in Figure 12 of the drawings.

Referring to Figure 13, after the suture elements 160 have been placed through the target vessel 182 as described above, the device 112 can be removed from a surgical site 190, at which the anastomosis is to be formed, and held at a convenient location 192 remote from the surgical site 190 until the opposed ends 160.2 of the suture elements 160 supported on the suture support 118 of the device 114 have been placed through the donor vessel, as described in greater detail herein below. Conveniently, the device 112 can be held on an appropriate bracket, clamp, support, or the like, remote from the surgical site 190 and while the parts 116.1, 116.2 of its suture holder 116 are held thereon. In the case where a sternotomy 193 has been performed, for example, to provide access to the heart for performing the CABG procedure, the device 112 can be held on a

support, or the like, mounted on a bracket 194 holding the sternotomy 193 in an open condition. An appropriate support for holding the device 112 at a position 192 remote from the surgical site 190, is disclosed in Applicant's co-pending Patent Application No. 09/608,832, filed on June 6th, 2000, entitled "Support Clamp", the full disclosure of which is herein incorporated by reference.

As the device 112 is removed from the surgical site 190 after placement of the suture elements through the target vessel, portions of the suture elements 160 contained in the suture container portion 121.3 of the elongate flexible member 120 and adjacent the device 112 are drawn from the lumen 121.4 through the slit 121.5, as can best be understood with reference to Figures 2A and 13 of the drawings.

Referring to Figure 14, after the ends 160.1 of the suture elements 160 have been placed through the target vessel 182, and the device 112 has been positioned remote from the surgical site as described above, the opposed ends 116.2 of the suture elements 160 are placed through the donor vessel. The donor vessel is generally indicated by reference numeral 196 in Figure 14. The ends 160.2 are placed through the donor vessel 196 in a fashion similar to that described above, but using the device 114. After the device 114 has been used to place the opposed ends 160.2 of the suture elements 160 through the donor vessel 196, it is removed from the surgical site 190. As it is removed, and as can best be understood with reference to Figures 2A and 13 of the drawings, portions of the suture elements 160 contained in the suture container portion 121.3 of the elongate flexible member 120 and adjacent the device 114 are drawn from the lumen 121.4 and through the slit 121.5. By having retained the portions of the suture elements 160 in the suture container portion 121.3 of the elongate flexible member 120 in this fashion, the portions were inhibited from becoming entangled during the placement of the suture elements in the target and donor vessels respectively. After the device 114 has been used to pass the opposed ends 160.2 of the suture elements 160 through the donor vessel 196, it too can be supported at a convenient location remote from the surgical site 190, in a fashion similar to that described above with reference to the device 112. Instead, the device 114 can be held in a user's hand, or otherwise positioned, remote from the surgical site 190.

In Figure 14, only the parts 116.1, 116.2 of the suture holders 116, 116 of the respective devices 112, 114 are shown for the sake of clarity and after the opposed ends 116.2 of the suture elements 160 have been passed through the donor vessel 196 by the device 114. Typically, immediately after the suture elements 160 have been placed

through the target and the donor vessels respectively, the suture holder 116 of each device 112, 114 is held on the shaft portions 118.2, 118.2 of their associated suture holders 118, 118 as described above.

The parts 116.1, 116.2 of the suture holder 116 of each device 112, 114 are then removed from the shaft portions 118.2, 118.2. It will be appreciated that each of the suture elements 160 extends between one of the parts 116.1, 116.2 of the suture holder 116 of the device 112 and one of the parts 116.1, 116.2 of the suture holder 116 of the device 114. As indicated in the drawings, five suture elements 160 extend between the part 116.1 of the suture holder 116 of the device 112 and the part 116.1 of the suture holder 116 of the device 114. Furthermore, five suture elements 160 extend between the part 116.2 of the suture holder 116 of the device 112 and the part 116.2 of the suture holder 116 of the device 114. In the present application, namely to form a side-to-side anastomosis during a CABG procedure, it has been found that a total of ten suture elements 160 is sufficient to form a typical side-to-side anastomosis. However, it will be appreciated that the system 110 can be provided with any appropriate number of suture elements depending on the intended application for which the system is to be used.

After the parts 116.1, 116.2 of the holders 116, 116 of the devices 112, 114 have been removed from the bodies 115, 115 of the devices 112, 114, the part 116.1 of the holder 116 of the device 112 is paired with the part 116.1 of the holder 116 of the device 114, so that the opposed ends 160.1, 160.2 of the five suture elements extending between the parts 116.1, 116.1 are paired up with each other. Figures 15 and 15A show the part 116.1 of the suture holder 116 of the device 112 paired with the part 116.1 of the suture holder 116 of the other device 114. In this fashion, the opposed ends of the same suture elements are paired with each other. In Figure 15, each of the five suture elements extending between the parts 116.1, 116.1 are indicated by reference numerals 160A, 160B, 160C, 160D and 160E. The opposed ends of the suture elements are indicated by reference numerals 160.1A and 160.2A, 160.1B and 160.2B, 160.1C and 160.2C, 160.1D and 160.2D, and, 160.1E and 160.2E. The parts 116.2, 116.2 are not shown in Figure 15 for the sake of clarity.

Conveniently, the parts 116.1, 116.2 of the suture holders 116, 116 can bear an appropriate form of identification to ease the task of determining which of the parts 116.1, 116.2 of the device 112 carries the opposed ends of the suture elements carried on which of the parts 116.1, 116.2 of the device 114. For example, the parts 116.1, 116.2 of the holders 116, 116 can be distinctively colored to enable a user to

determine readily which part 116.1, 116.2 belongs with which other part 116.1, 116.2. For instance, presuming the part 116.1 of the device 112 carries an end of each of five of the suture elements and the part 116.1 of the device 114 carries the opposed ends of the same five suture elements, then the parts 116.1, 116.1 can typically be of the same color, such as black, for example. The other part 116.2 of the device 112 then carries an end of each of the five other suture elements and the part 116.2 of the device 114 then carries the opposed ends of the same five other suture elements. The parts 116.2, 116.2 can then be of the same color but a color different to the color of the parts 116.1, 116.1. For example, they can be colored white.

After the opposed ends 160.1, 160.2 of the suture elements 160 on the suture holder parts 116.1, 116.1 have been paired in this fashion, the opposed ends of each suture element can be disengaged from the needles 117 and tied together to form sutures joining the target vessel 182 and the donor vessel 196 together adjacent their apertures thereby to form a side-to-side anastomosis between them. Tying of the suture elements can be performed manually. Instead, appropriate suture tying devices can be used. Advantageously, use can be made of an appropriate suture-handling device to render the task of tying the opposed portions of the suture elements together more manageable. An example of such a suture-handling device is disclosed in Applicant's co-pending Patent Application No. 09/610,099, filed on June 6th, 2000, entitled "Suture Comb" the full disclosure of which is herein incorporated by reference.

Such a suture-handling device is indicated by reference numeral 210 in Figures 16 and 17. As indicated, the device 210 has five slots 210.1, 210.2, 210.3, 210.4 and 210.5. The slots 210.1, 210.2, 210.3, 210.4, 210.5 diverge outwardly relative to one another in a direction away from a leading end 212 of the device 210. Each slot 210.1, 210.2, 210.3, 210.4, 210.5 has a mouth 210.1A, 210.2A, 210.3A, 210.4A, 210.5A at the end 212. The mouths are laterally spaced apart relative to one another by a distance corresponding to spacings between the paired up ends of the suture elements 160. As can best be seen with reference to Figure 16, since the spacing between the mouths 210.1A, 210.2A, 210.3A, 210.4A, 210.5A corresponds with the spacing between the paired up ends of the suture elements on the parts 116.1, 116.1, the suture-handling device 210 can readily be passed laterally across paired portions of the suture elements 160 adjacent their ends, as indicated by arrow J. As the suture-handling device 210 is passed laterally across the paired portions of the suture elements 160 in this fashion, the paired end portions of the suture elements enter the mouths 210.1A, 210.2A, 210.3A, 210.4A,

210.5A and ride along the slots 210.1, 210.2, 210.3, 210.4, 210.5. As the paired end portions ride along the diverging portions of the slots 210.1, 210.2, 210.3, 210.4, 210.5 of the device 210, the paired portions become spaced laterally further apart relative to one another, as indicated by the arrows I in Figure 17 of the drawings. By increasing the lateral spacing between the paired end portions of the suture elements 160 in this fashion, manual pick up of the opposed end portions of the individual suture elements is made easier and more manageable. Advantageously, the device 210 is arranged to retain the paired end portions thereon after the lateral spacing between the paired up end portions has been increased. In this way, the paired up end portions can be held in paired relationships so that each set of paired up end portions can be picked up from the device 210 separately of the others and tied together, while the end portions of the other suture elements are retained in paired relationships on the device 210.

It will be appreciated that the parts 116.2, 116.2 can be paired up in a similar fashion to that described above with reference to the parts 116.1, 116.1. Thereafter, another device, similar to the device 210, can be used to hold the paired up end portions of the other suture elements together, so that they too can be picked up separately and tied, while the paired up end portions of the other suture elements are held in paired up relationships on the other device 210.

Referring to Figure 18, the target vessel 182 and the donor vessel 196 are shown in a position adjacent each other and ready for the opposed ends 160.1, 160.2 of the suture elements 160 to be tied together, thereby to form sutures extending between the walls of the vessels 182, 196. The vessels can be brought into a position adjacent each other manually, while pulling opposed portions of the suture elements 160. In this way the vessels can be caused to ride along the suture elements 160 until they are positioned as schematically shown in Figure 18. Thereafter, the opposed ends of the suture elements can be tied together to form sutures joining the vessels together so as to form the side-to-side anastomosis between them. After the sutures have been tied, or secured, a side-to-side anastomosis similar to the side-to-side anastomosis shown in Figure 1C is formed between the vessels 182, 196.

A suture placement system, in accordance with the invention, which can be used advantageously to form an end-to-side anastomosis, as indicated in Figure 1B of the drawings, will now be described with reference to Figures 19 to 28. In Figures 19 to 28 like reference numerals have been used to designate similar parts and features unless

otherwise stated. Furthermore, the system 310 is used in a fashion similar to that of the system 110, unless otherwise stated.

As can best be seen with reference to Figure 19 of the drawings, the suture placement system, which is generally indicated by reference numeral 310, is similar to the system 110, save that instead of the device 114, the system 310 has a different suture placement device. The different suture placement device is indicated generally by reference numeral 312 and is arranged for placing sutures through a vessel wall adjacent a mouth of a vessel, as will be described in greater detail herein below.

Referring to Figure 20 of the drawings, the suture placement device 312 comprises a body 314 and two suture holder retainers 316, 318. Each retainer 316, 318 is mounted on the body 314 by means of a pivotal connection 320, 322 respectively. The device 312 further comprises a vessel support shaft 324 for receiving an end portion of a vessel, or graft, or the like, thereon. The shaft 324 is mounted on the body 314. The shaft 324 is arranged to be passed through the mouth of the vessel so that the vessel can be supported at an operative position on the shaft 324 at which position the device 312 can pass a plurality of suture elements through the wall of the vessel adjacent its mouth.

The body 314 comprises a piston and cylinder arrangement similar to that of the devices 112, 114 described above. The piston and cylinder arrangement is indicated schematically and generally by reference numeral 326. A socket for receiving an end of the conduit portion 121.2 of the flexible elongate member 120 is indicated at 327. When the conduit portion 121.2 is connected to the socket 327, a chamber within the body 314 is connected in fluid flow communication with a female Luer-type connector in a fashion similar to that of the device 114 in the system 110.

Referring now to Figures 21 to 23 of the drawings, the shaft 324 defines a plurality of longitudinally extending passages indicated schematically by reference numeral 328. The passages 328 have bends 330 leading to mouths 332 opening at an outer surface 334 of the shaft 324. As can best be seen with reference to Figures 22 and 23, a needle 335 is received in each of the passages 328. Each needle 335 defines a pointed end 335.1. An actuation member in the form of an elongate pin or rod formation 336 is received in each of the passages 328 immediately behind the needles 335. The pin formations 336 are operatively associated with the piston on the body 314 so that the formations 336 are caused to advance, as indicated by arrow K, in response to the piston being caused to advance within its associated cylinder. It will be appreciated that the piston of the device 312 is caused to advance within its associated cylinder in a manner

similar to that of the piston and cylinder arrangement of the devices 112, 114 as described above, namely, by depressing a plunger of a syringe connected in fluid flow communication with the female Luer-type connector 140, as can best be seen with reference to Figure 19.

5 With reference to Figure 23, upon advancement of the pin formations 336 along the passages 328, the needles 335 are caused to advance along the passages 328 also. The needles 335 are caused to advance such that their pointed ends 335.1 are pushed out of the mouths 332 and laterally outwardly from the surface 334 of the shaft 324.

10 Referring now to Figure 24 of the drawings, ends 338.1 of a plurality of suture elements 338 are operatively engaged to end portions of the needles 335 adjacent the ends 335.1 of the needles 335. The ends 338.1 of the suture elements 338 can be operatively engaged to the end portions of the needles 335 in any appropriate manner. For example, the end portions of the needles 335 can have laterally extending apertures
15 through which end portions of the suture elements 338 can be threaded. The suture elements 338 typically extend along the outer surface 334 of the shaft 324, along an outer surface of the body 314 and into the suture container portion 120.3 of the elongate flexible member 120, as can best be seen with reference to Figure 19 of the drawings, in a fashion similar to that described above with reference to the system 110. It will be
20 appreciated that opposed ends of the suture elements 338 are held on the suture support 118 of the device 112 of the system 310 in a fashion similar to that of the ends 160.1 of the suture elements 160 of the system 110.

 The operation of the device 312 will now be described with reference to Figures 25 to 27 of the drawings. It will be appreciated that opposed ends of the suture
25 elements 338 are placed through a vessel wall by means of the device 112 and adjacent an incision in that vessel wall in a manner similar to that described above with reference to the system 110.

 Referring to Figure 25, an end portion 350.1 of a vessel, or graft, indicated generally by reference numeral 350, is shown in a received condition on the shaft 324.
30 The end portion 350.1 of the vessel 350 was positioned on the shaft 324 by displacing the suture holder arrangements 316, 318 angularly about the pivotal connections 320, 322 into open positions and then passing the end portion 350.1 of the vessel 350 over the shaft 324. Conveniently, marks 352 are provided on the shaft 324 to indicate an appropriate position of an end 350.3 of the vessel 350 on the shaft 334 so as to enable the suture

elements to be passed through a vessel wall 350.2 of the vessel 350 at an appropriate distance from the end 350.3. In Figure 25, only the suture holder retainer 318 is shown in an open condition. Typically, both retainers 316, 318 are opened so as to pass the vessel portion 350.1 over the shaft 324. When the end portion 350.1 of the vessel 350 has been positioned such that its end 350.3 is in register with the marks 352 on the shaft 324, the retainers 316, 318 are displaced angularly about the pivotal connections 320, 322 into a closed condition in which the end portion 350.1 of the vessel 350 is embraced between the retainers 316, 318 and the shaft 324. Figure 25 shows the retainer 316 having been displaced from an open condition into a closed condition after the portion 350.1 of the vessel 350 has been appropriately positioned on the shaft 324.

Conveniently, the vessel 350 is shaped to have an angled, or inclined, end 350.3 so as to permit an end-to-side anastomosis to be formed in which the one vessel extends from the other at an acute angle, as can best be seen with reference to Figure 1B of the drawings. The marks 352 are formed on the shaft 324 to extend circumferentially around the shaft 324 so as to align with a vessel having such an inclined end 350.3.

Figure 26 shows the portion 350.1 of the vessel 350 having been received on the shaft 324 and further shows both retainers 316, 318 in closed conditions. As can best be seen with reference to Figure 25 of the drawings, the retainers 316, 318 are provided with cooperating engaging formations so as to lockingly engage with each other when in their closed conditions. Conveniently, the engaging formations comprise tongue members 354, 354 and slot arrangements 356, 356 for snap-lockingly receiving the tongue members 354, 354. After the end portion 350.1 of the vessel 350 has been received on the shaft 324 and the retainers 316, 318 have been closed so as to engage lockingly with each other, the needles 335 bearing the ends 338.1 of the suture elements 338 are caused to advance along the passages 328. This is achieved by means of the pin formations 336 being displaced along the passages 328 in response to actuating a syringe connected in fluid flow communication with the female Luer-type connector 140 operatively associated with the device 312. As the needles 335 are caused to advance in this fashion, the ends 335.1 of the needles 335 are driven through the wall 350.2 of the vessel 350 adjacent its mouth. The ends 338.1 of the suture elements 338 are passed through the vessel wall 350.2 together with the ends 335.1 of the needles 335, since the ends 338.1 of the suture elements 338 are appropriately attached to the ends of the needles. After the ends 335.1 of the needles 335 have passed through the vessel wall 350.2, the ends 335.1 are driven into suture holders 358, 360 releasably mounted on the

5 suture holder arrangements 316, 318 to be held captive by the holders 358, 360. The retainers 316, 318 are then angularly displaced about the pivotal connections 320, 322 into their open conditions to enable the vessel 350 to be removed from the shaft 324. The suture holders 358, 360 are removed from the retainers 316, 318, while the needle ends 335.1, and consequently also the ends 338.1 of the suture elements 338, are held captive on the suture holders 358, 360. To remove the holders 358, 360 from the retainers 316, 318, hand grippable portions 358.1, 360.1 of the holders 358, 360 are typically manipulated to cause the holders 358, 360 to be slid along slots 362 defined by the retainers 316, 318. As can best be seen in Figure 24 of the drawings, each retainer 316, 318 has a part annular shoulder formation 364 arranged to retain the holders 358, 360 in a mounted condition on the retainers 316, 318. When the holders 358, 360 are removed from their associated retainers 316, 318, the hand grippable portions 358.1, 360.1 are manipulated resiliently to urge the holders over the annular shoulder formations 364. Figure 28 shows the end portion 350.1 of the vessel 350 having been removed from the shaft 324 and further shows the holders 358, 360 having been removed from the associated retainers 316, 318.

Referring now to Figures 28A and 28B of the drawings, the suture holder 358 is shown in greater detail, and after it has been removed from its associated retainer 316. In Figures 28A and 28B, the holder 358 is shown after the needles 335 have been passed through the portion of the vessel 350 and into engagement with the holder 358. In Figure 28A, the suture holder is shown having a shape corresponding to the shape which it has when mounted on its associated retainer 316. When mounted on the retainer 316, opposed flange portions 358.2 of the suture holder 358 are held in a resiliently deformed condition such that an inner surface 358.3 defined by the flange portions 358.2 extends generally along a circular circumference so as to extend snugly around the vessel portion 350.1 when held between the retainers 316, 318 and the shaft 324. The suture holder 358 is typically made from a resilient material, such as silicone, or the like. In Figure 28B, the suture holder 358 is shown after having been removed from its associated retainer 316. After having been removed, the flange portions 358.2 take up a relaxed condition in which they have a straighter profile than in the case when mounted on the retainer 316. In this relaxed condition, the spacing between the needle ends 335.1 on which the ends 338.1 of the suture elements 338 are carried is greater than in the case when the holder 358 was mounted on the retainer 316. The holder 358 is designed so that when in its relaxed condition, the spacing between adjacent suture element ends 338.1 on the needles

335 generally corresponds with the spacing between adjacent suture element ends when held on the parts 116.1, 116.2 of the suture holder of the device 112.

To form the end-to-side anastomosis, the device 112 is used to place the opposed ends of the suture elements 338 through another vessel wall adjacent an incision in the other vessel wall in a fashion similar to that described above with reference to the system 110.

After the suture elements 338 have been placed through the wall of the portion 350.1 of the vessel 350 adjacent its mouth, as described above, and after opposed ends of the suture elements 338 have been placed through a vessel wall adjacent an incision in the vessel wall by the device 112, in a manner similar to that described above, the suture holders 358, 360 are paired up with the suture holders 116.1, 116.2 of the device 112. Conveniently, the holders 116.1, 116.2 and 358, 360 are distinctively colored to indicate to the user which of the holders 116.1, 116.2 is to be matched up with which of the holders 358, 360. For example, the holders 358 and 116.1 can be of the same color e.g. white, or the like, and the holders 360 and 116.2 can be of the same color, but of a different color than the holders 358 and 116.1. For example, the holders 360 and 116.2 can be black, or the like, for example. Accordingly, in this fashion, opposed ends of the same suture elements are paired up with each other. The paired up end portions of the suture elements can then be passed into the slots of a suture handling device as described above, for example. After having been received in the slots of the suture handling device as described above, the suture elements can be removed from the suture handling device and can be tied, or otherwise secured together, so as to form sutures between the vessels thereby to form an end-to-side anastomosis between the vessels.

Although certain embodiments of the invention have been described above in detail for purposes of clarity and understanding, it will be appreciated that the invention has been described with reference to the above embodiments by way of example only, and that modifications or changes can be made without detracting from the essence of the invention. For example an embodiment of the system of the invention can be provided having two devices similar to the device 312 for use in forming end-to-end anastomose. accordingly, the scope of the invention is defined by the appended claims with due regard to equivalents of the claimed elements or features.

WHAT IS CLAIMED IS:

1 1. A method of suturing patient tissue together, the method
2 comprising:
3 positioning a suture placement device adjacent patient tissue, the suture
4 placement device having a body and a suture holder releasably attached on the body;
5 actuating the suture placement device;
6 causing the suture placement device to pass an end portion of at least one
7 suture element through patient tissue in response to actuating the suture placement device;
8 causing the end portion of the at least one suture element to be held on the
9 suture holder of the device after the end portion has been passed through the patient
10 tissue; and
11 detaching the suture holder from the body of the device while the end
12 portion of the at least one suture element is held thereon.

1 2. The method of claim 1, wherein the patient tissue comprises a
2 vessel wall having an aperture extending there through, positioning the suture placement
3 device adjacent patient tissue comprising positioning the suture placement device to
4 extend through the aperture.

1 3. The method of claim 2, wherein causing the suture placement
2 device to pass an end portion of the at least one suture element through patient tissue
3 comprises causing the suture placement device to pass the end portion of the at least one
4 suture element through the vessel wall adjacent one side of the aperture.

1 4. The method of claim 3, which comprises causing the suture
2 placement device to pass an end portion of another suture element through the vessel wall
3 adjacent an opposed side of the aperture in response to actuating the suture placement
4 device.

1 5. The method of claim 4, wherein the suture holder of the device has
2 two parts, the method comprising causing the end portion of the one suture element to be
3 held on the one part of the suture holder and the end portion of the other suture element to
4 be held on the other part of the suture holder after the end portions of the suture elements
5 have been passed through the vessel wall.

1 6. The method of claim 5, wherein detaching the suture holder from
2 the body of the suture placement device comprises detaching both parts of the suture
3 holder from the body while the end portion of the one suture element is held on the one
4 part and the end portion of the other suture element is held on the other part.

1 7. The method of claim 6, which further comprises positioning
2 another suture placement device to extend through an aperture in another vessel wall.

1 8. The method of claim 7, which further comprises actuating the other
2 suture placement device to cause the other suture placement device to pass opposed ends
3 of the suture elements through the other vessel wall, such that the opposed end portion of
4 the one suture element extends through the other vessel wall adjacent one side of its
5 aperture and the opposed end portion of the other suture element extends through the
6 other vessel wall adjacent an opposed side of its aperture.

1 9. The method of claim 8, wherein the other suture placement device
2 comprises a body and a suture holder releasably attached thereto, the suture holder having
3 two parts, the method comprising causing the opposed end portion of the one suture
4 element to be held on the one part of the suture holder and the opposed end portion of the
5 other suture element to be held on the other part of the suture holder, after the opposed
6 end portions have been passed through the other vessel wall.

1 10. The method of claim 9, which further comprises detaching the
2 parts of the suture holder of the other suture placement device from its body while the
3 opposed end portions of the suture elements are held thereon.

1 11. The method of claim 10, which comprises bringing together the
2 part of the suture holder of the one suture placement device on which the end of the one
3 suture element is held and the part of the suture holder of the other suture placement
4 device on which the opposed end of that suture element is held, and bringing together the
5 other part of the suture holder of the one suture placement device on which the end
6 portion of the other suture element is held and the other part of the suture holder of the
7 other suture placement device on which the opposed end of the other suture element is
8 held.

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7 other suture placement device on which the opposed end of the other suture element is
8 held.

1 18. The method of claim 17, which comprises securing the end portion
2 of the one suture element to its opposed end portion and securing the end portion of the
3 other suture element to its opposed end portion after the parts of the suture holders have
4 been brought together, thereby to join the wall of the one vessel to the wall of the other
5 vessel to form an end to side anastomosis between the vessels.

1 19. A suture placement device comprising:
2 a body;
3 a support on the body, the support being arranged releasably to hold an end
4 of at least one suture element;
5 at least one engaging element displaceably mounted on the body, the
6 engaging element being arranged to pass through patient tissue so as to engage the end of
7 the at least one suture element when held on the support and to withdraw from the tissue
8 while the end of the suture element is engaged therewith, thereby to pass the end of the
9 suture element through the tissue; and
10 a suture holder on the body, the suture holder being arranged to hold the
11 end of the at least one suture element after it has been passed through the tissue, the
12 suture holder being releasably attached to the body so that the end of the at least one
13 suture element can be removed from the body by detaching the suture holder from the
14 body while the end of the at least one suture element is held thereon.

1 20. The suture placement device of claim 19, wherein the support is
2 arranged releasably to hold an end of each of a plurality of suture elements.

1 21. The suture placement device of claim 20, which further comprises
2 a plurality of engaging elements displaceably mounted on the body, each engaging
3 element being arranged to pass through tissue so as to engage one of the ends of the
4 suture elements when held on the support and to withdraw from the tissue while the end
5 of the suture element is engaged therewith, thereby to pass the end of the suture element
6 through the tissue.

1 22. The suture placement device of claim 21, wherein the suture holder
2 comprises two separate parts and wherein each part is arranged to hold an end of at least

one of the suture elements after the suture elements have been passed through the tissue, so that the ends of the suture elements can be removed from the body of the device by detaching both parts of the suture holder from the body while the ends of the suture elements are held thereon.

23. The suture placement device of claim 22, wherein the engaging elements are connected to the suture holder parts such that the ends of the suture elements are removable from the body by detaching the suture holder parts from the body while the ends of the suture elements are held on the engaging elements.

24. The suture placement device of claim 23, wherein the engaging elements are in the form of needles.

25. The suture placement device of claim 24, wherein the support defines a plurality of seats, the seats being arranged releasably to receive cuffs attached to ends of suture elements, the cuffs being arranged to engage with the needles.

26. A suture placement system comprising at least two suture placement devices, each device comprising:

- a body;
- a support on the body, the support being arranged releasably to hold an end of at least one suture element;
- at least one engaging element displaceably mounted on the body, the engaging element being arranged to pass through patient tissue so as to engage the end of the at least one suture element when held on the support and to withdraw from the tissue while the end of the suture element is engaged therewith, thereby to pass the end of the suture element through the tissue; and
- a suture holder on the body, the suture holder being arranged to hold the end of the at least one suture element after it has been passed through the tissue, the suture holder being releasably attached to the body so that the end of the at least one suture element can be removed from the body by detaching the suture holder from the body while the end of the at least one suture element is held thereon.

27. The suture placement system of claim 26, which comprises at least one suture element, one end of the suture element being releasably held on the support of

SYSTEMS, DEVICES AND METHODS FOR SUTURING PATIENT TISSUE

ABSTRACT OF THE DISCLOSURE

5 A method of suturing patient tissue together is provided. The method
comprises positioning a suture placement device adjacent patient tissue, the suture placement
device having a body and a suture holder releasably attached on the body. the method further
comprises actuating the suture placement device, causing the suture placement device to pass
an end portion of at least one suture element through patient tissue in response to actuating
10 the suture placement device and causing the end portion of the at least one suture element to
be held on the suture holder of the device after the end portion has been passed through the
patient tissue. The method further comprises detaching the suture holder from the body of
the device while the end portion of the at least one suture element is held thereon. A suture
placement device and a suture placement system which can be used in the method of the
15 invention are also provided.

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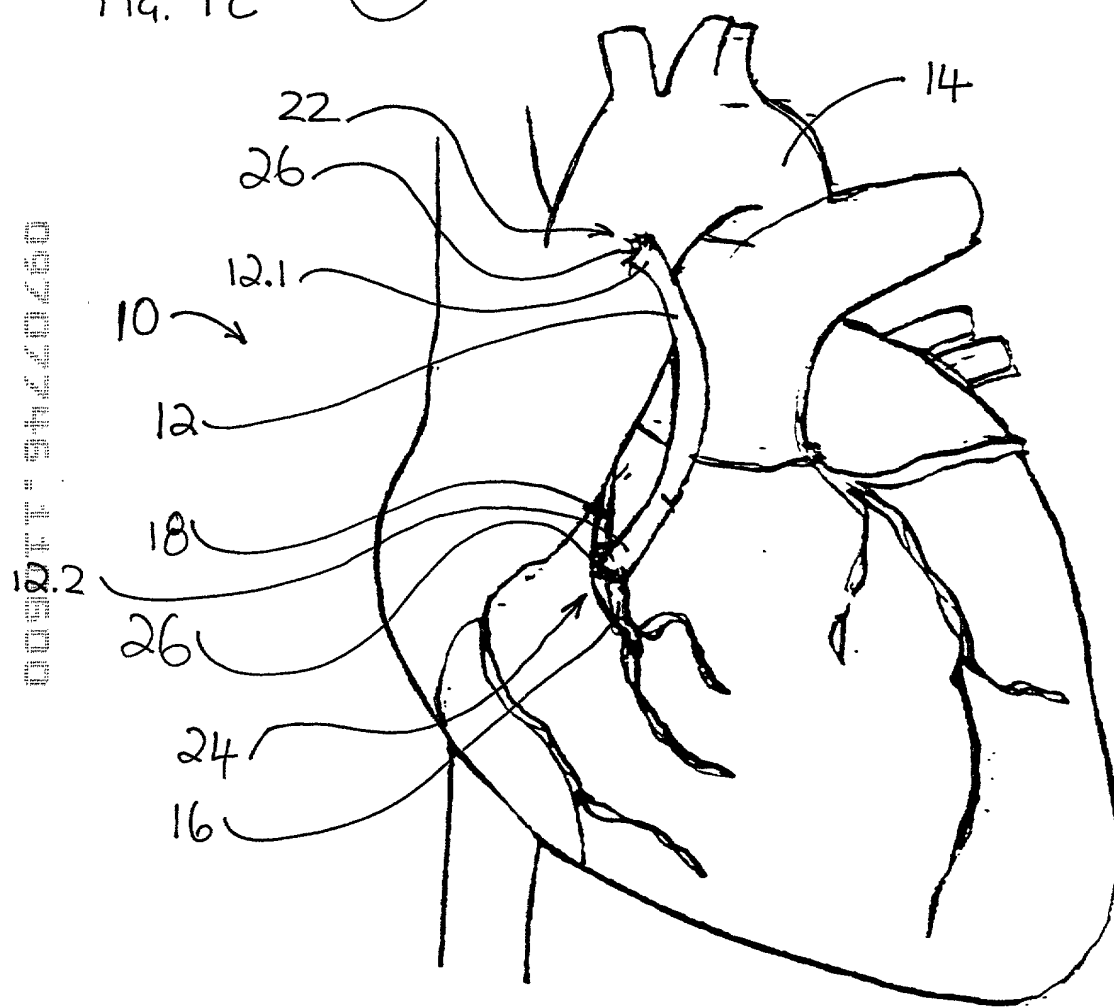
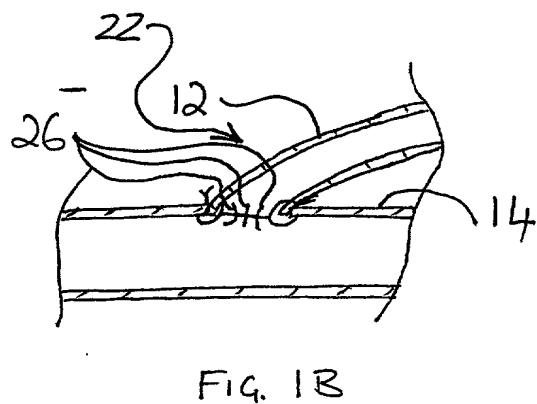
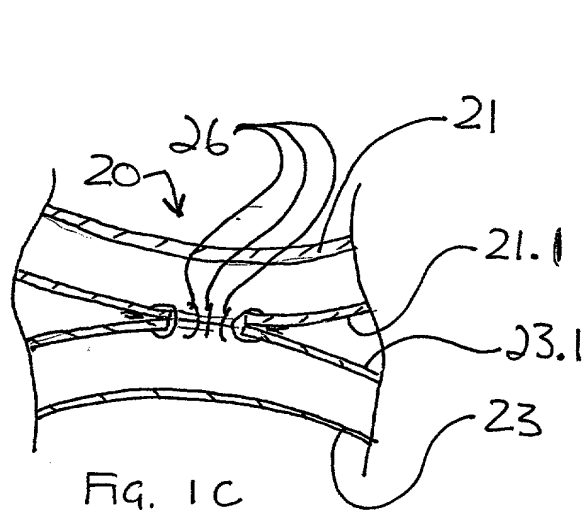
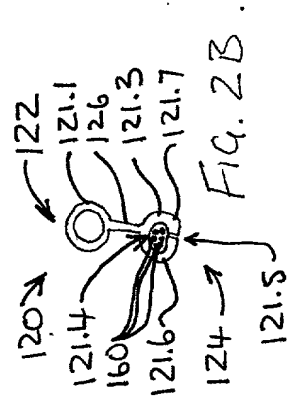
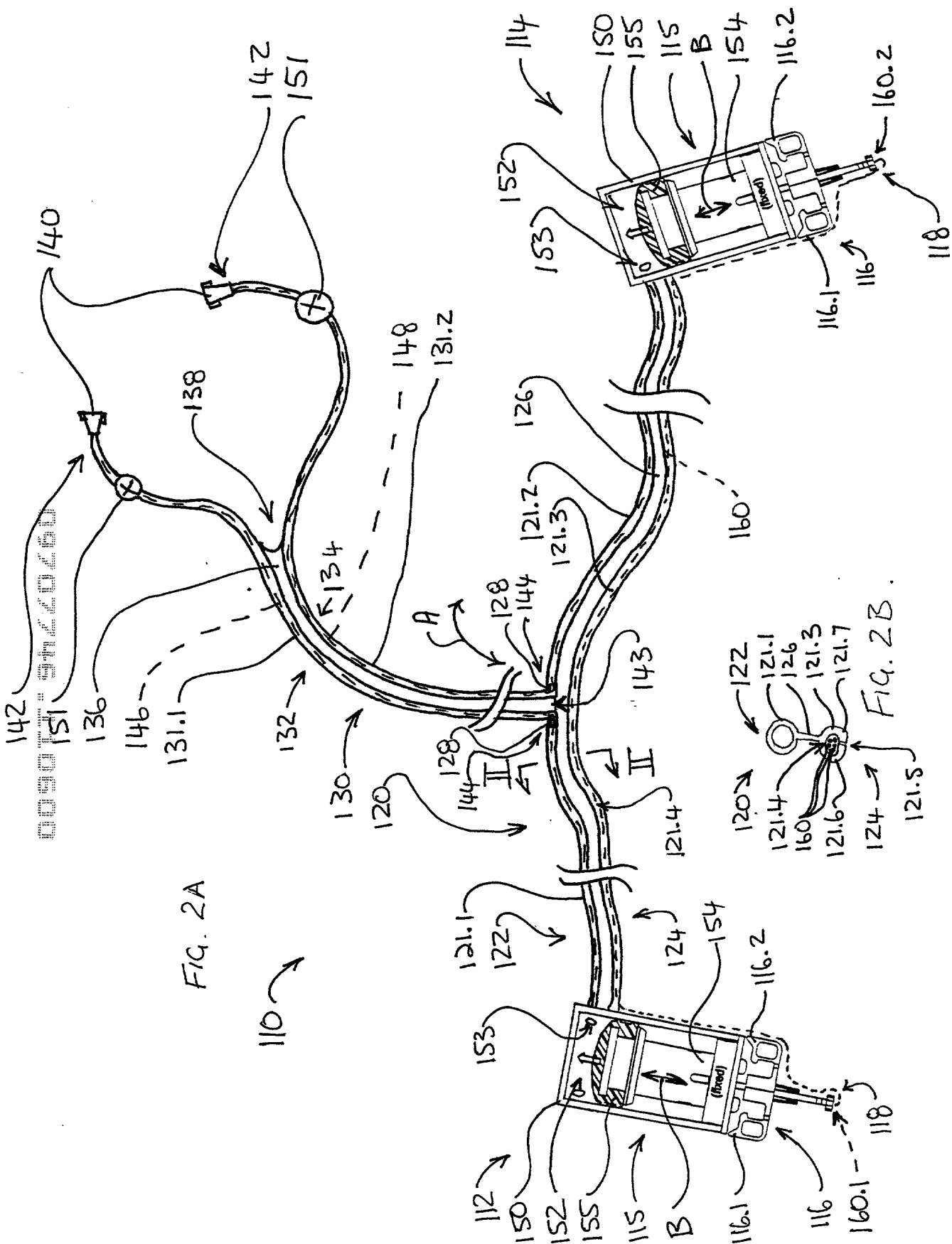


FIG. 1A

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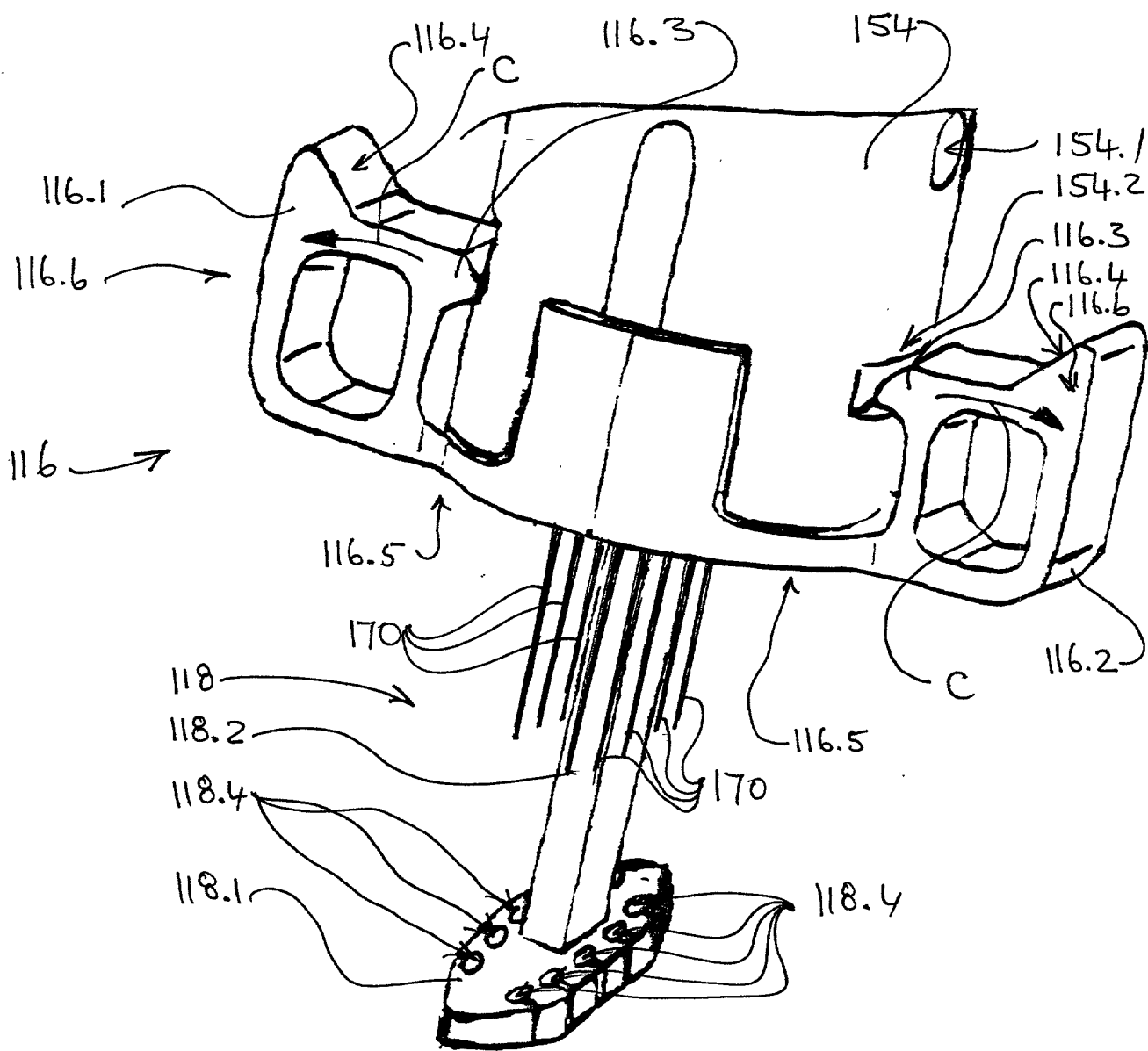
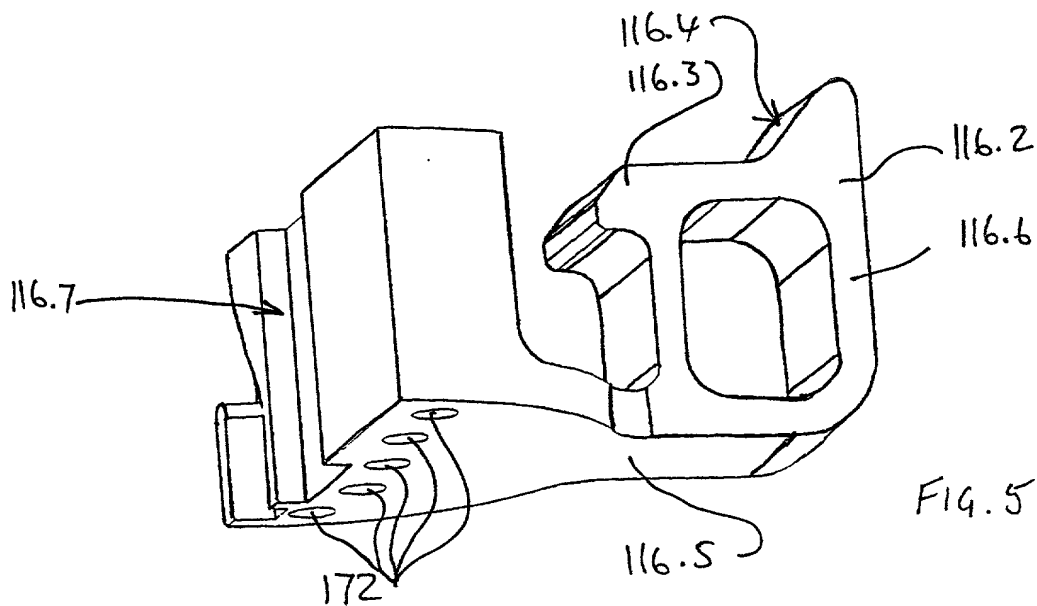
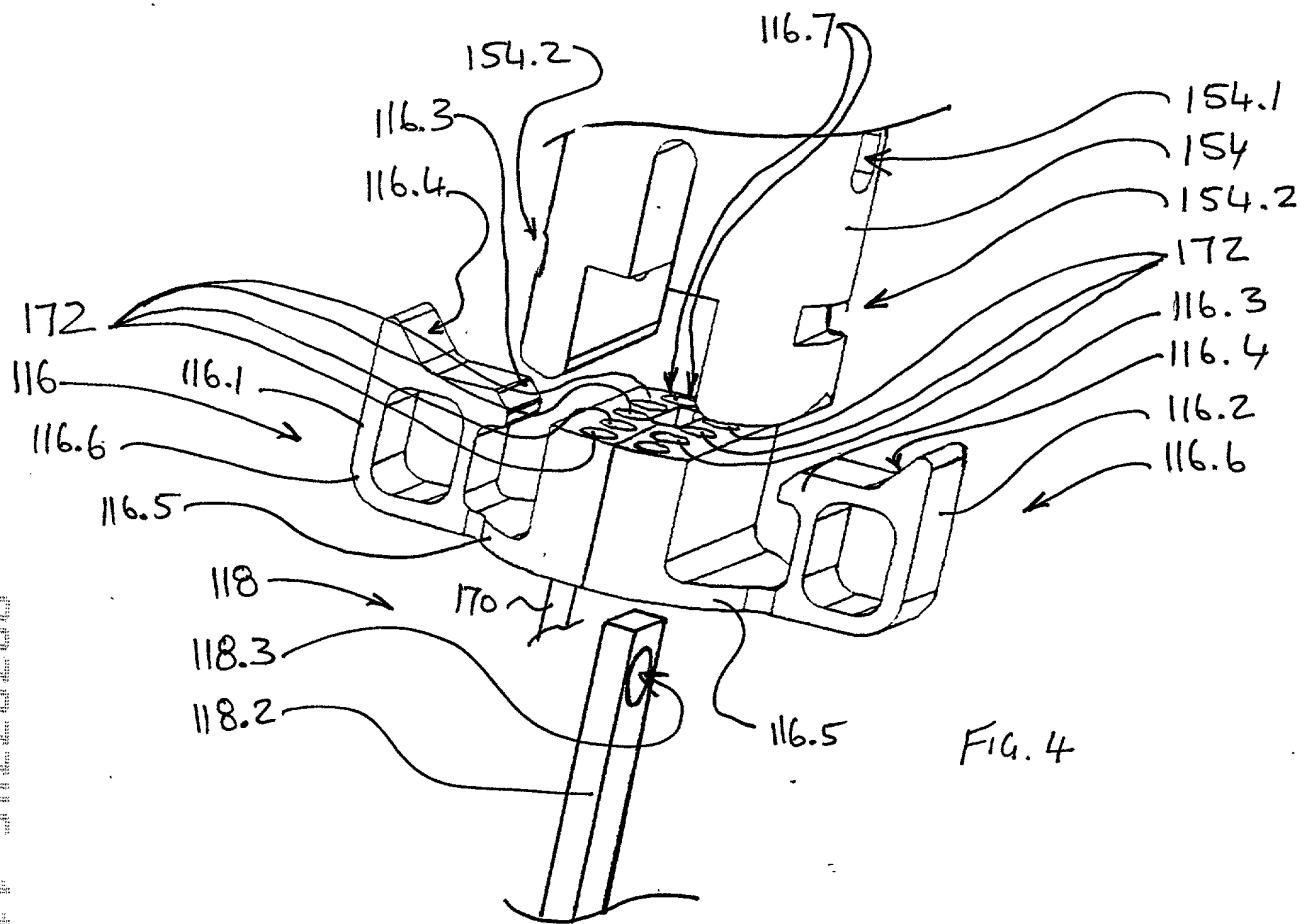
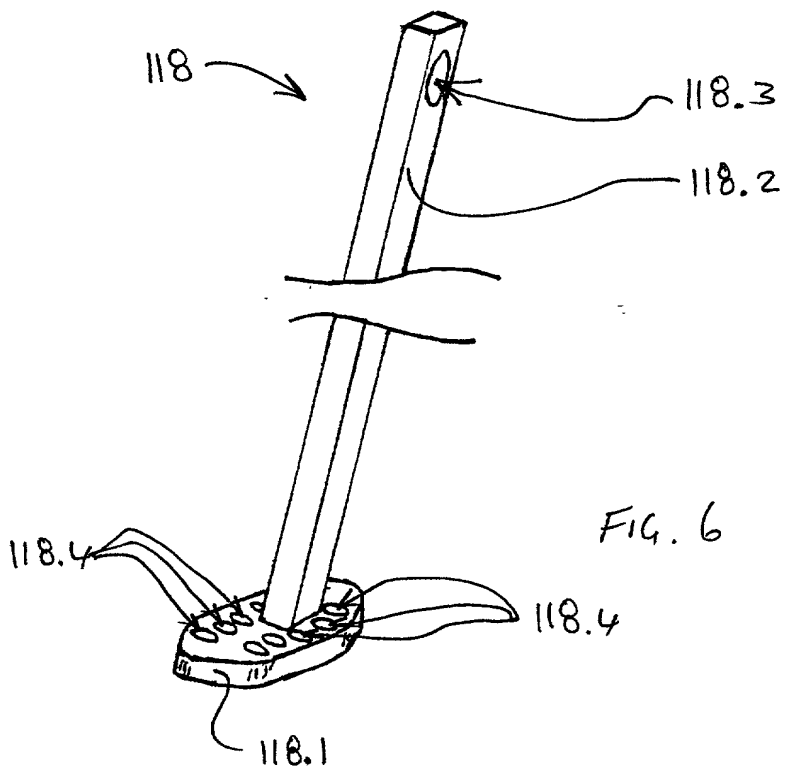
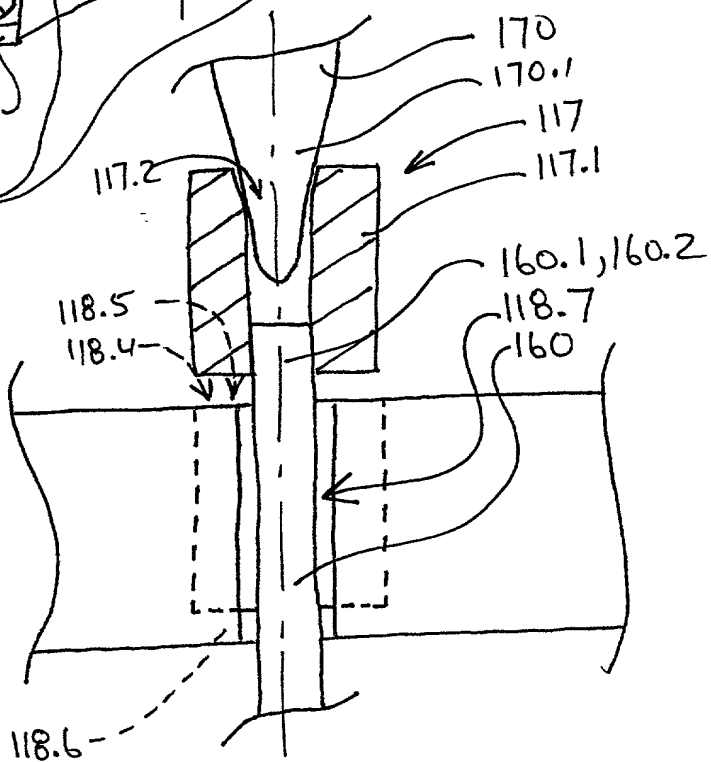
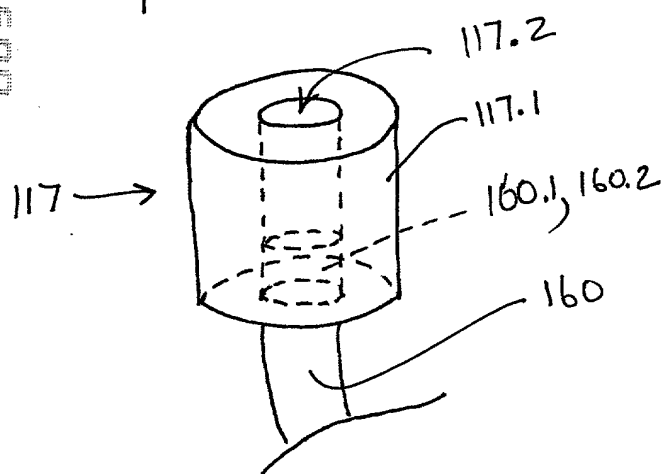
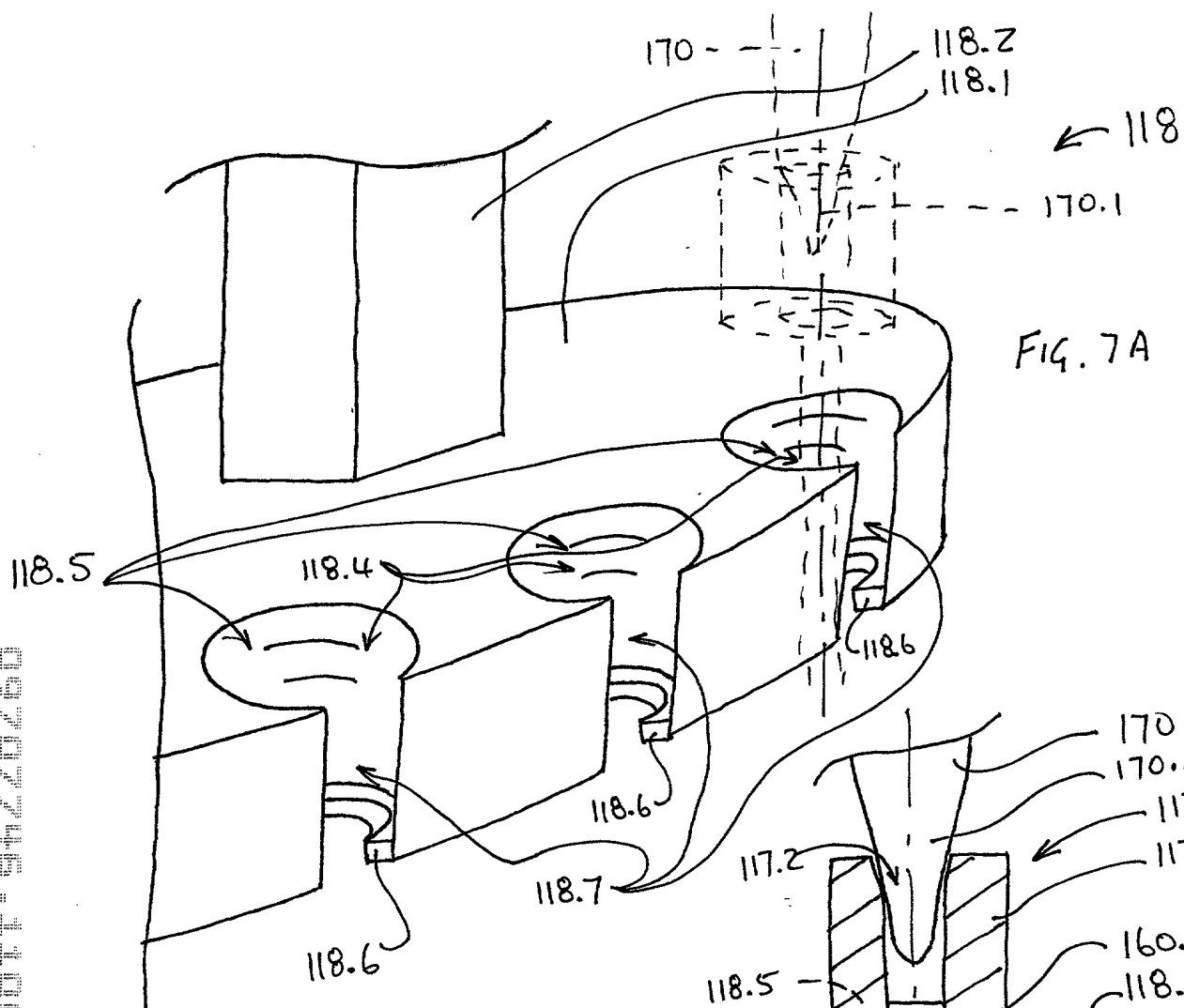


Fig. 3





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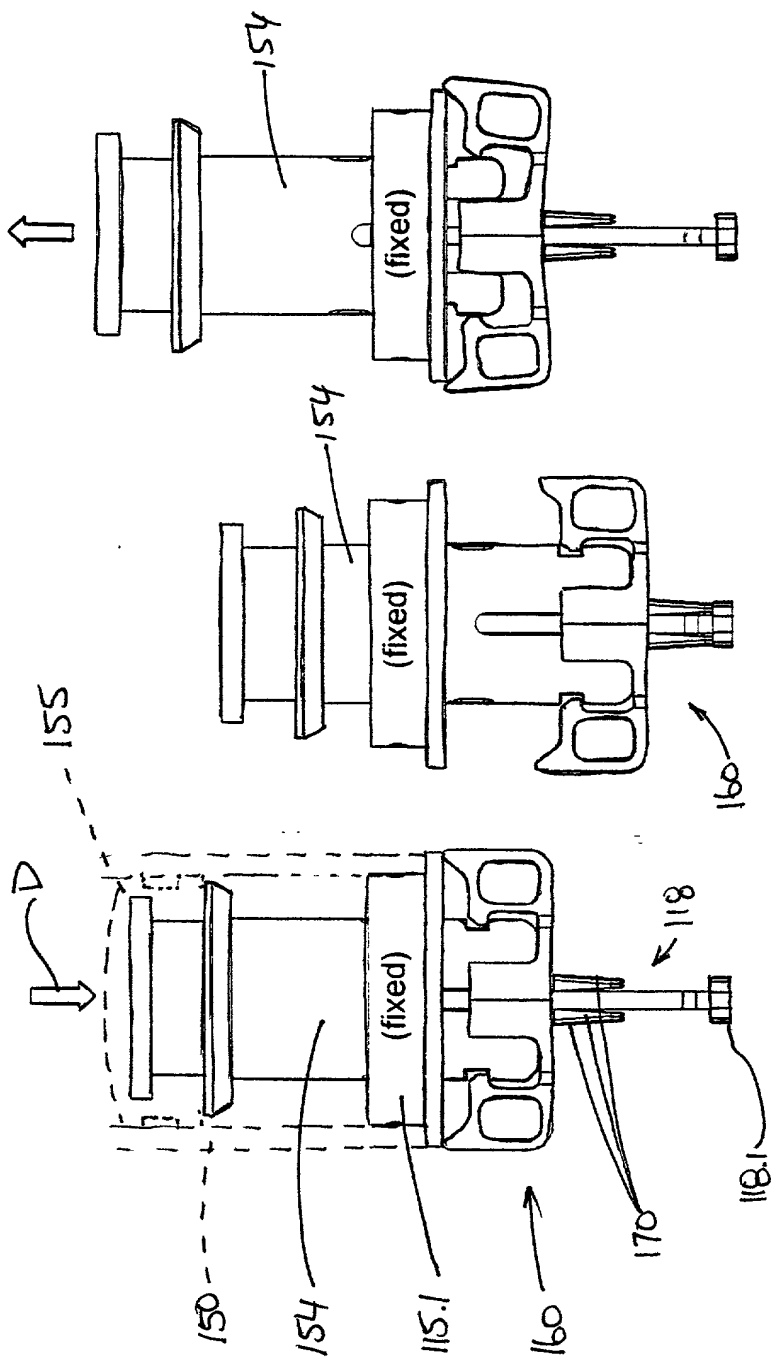


FIG. 8A

FIG. 8B

FIG. 8C

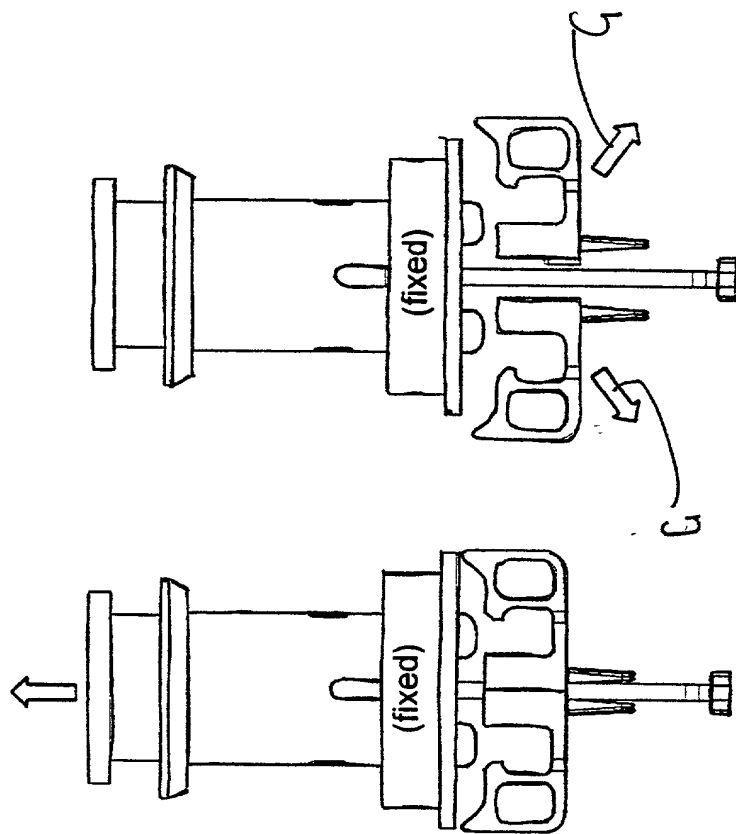
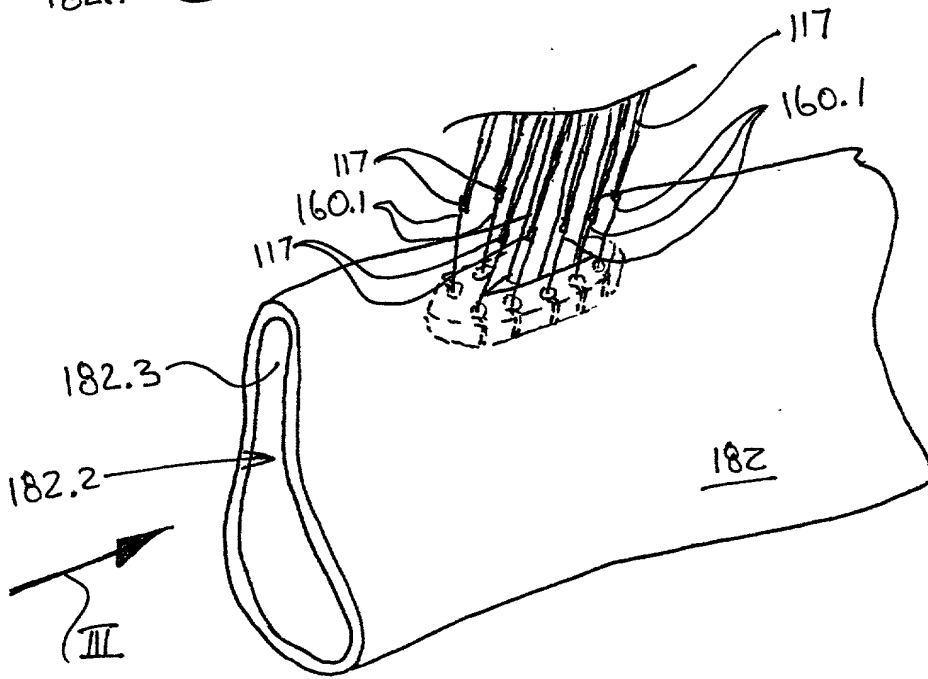
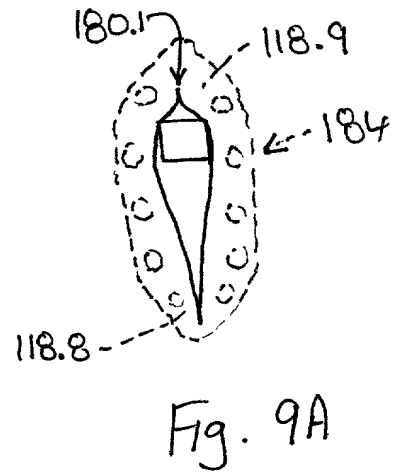
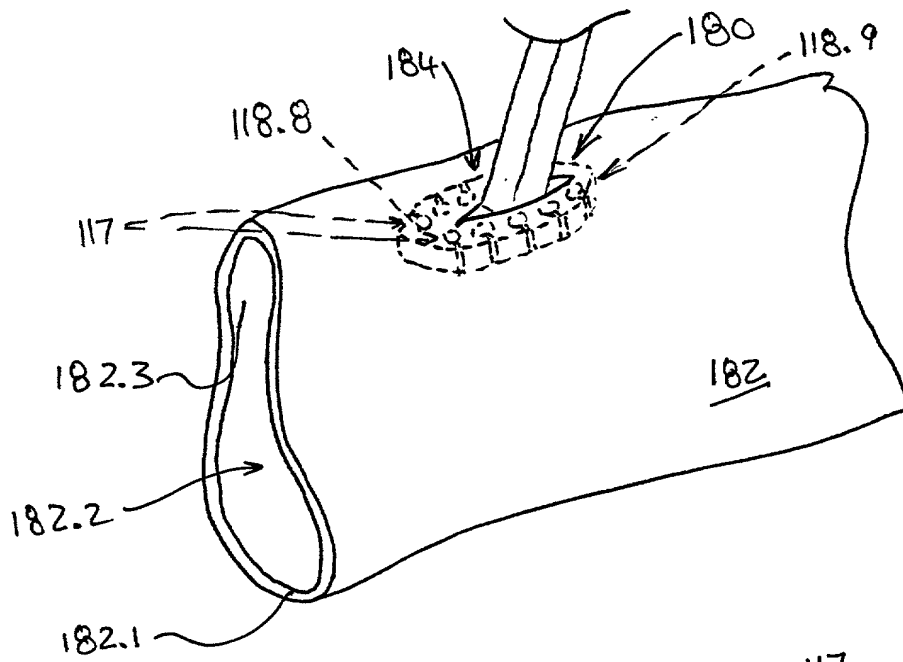


FIG. 8D

FIG. 8E

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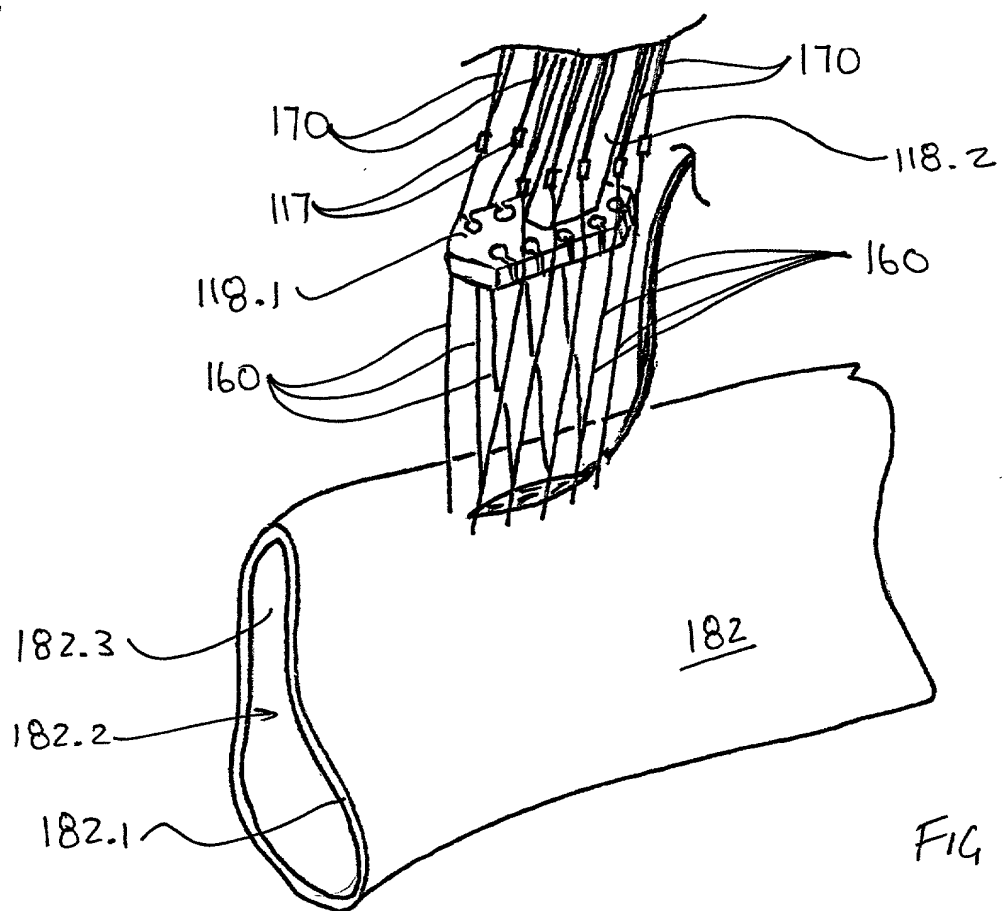


FIG 12

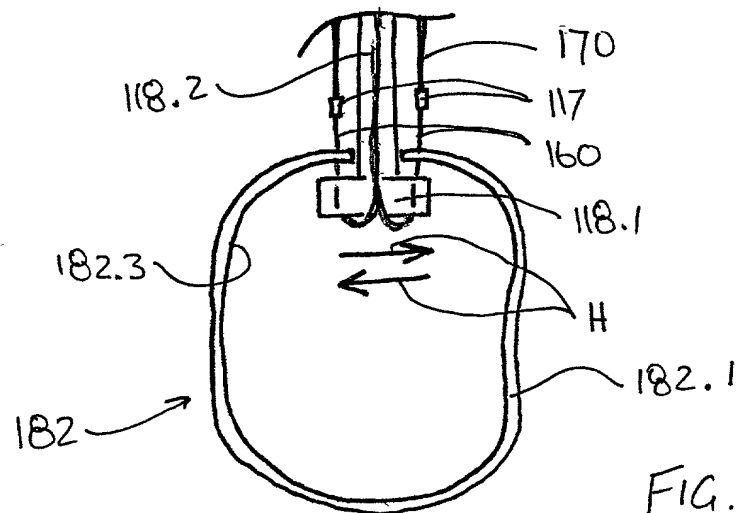


FIG. 11

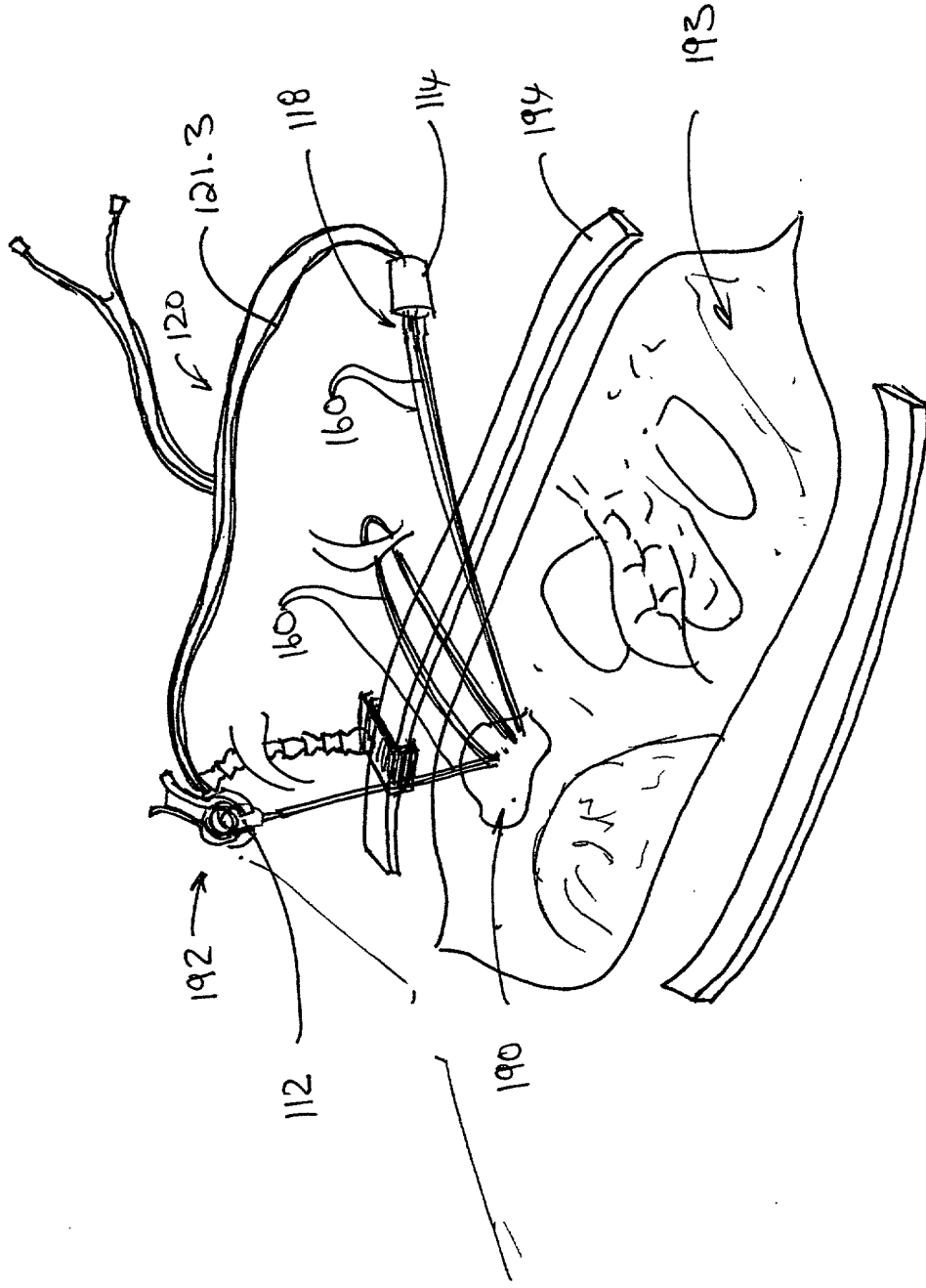
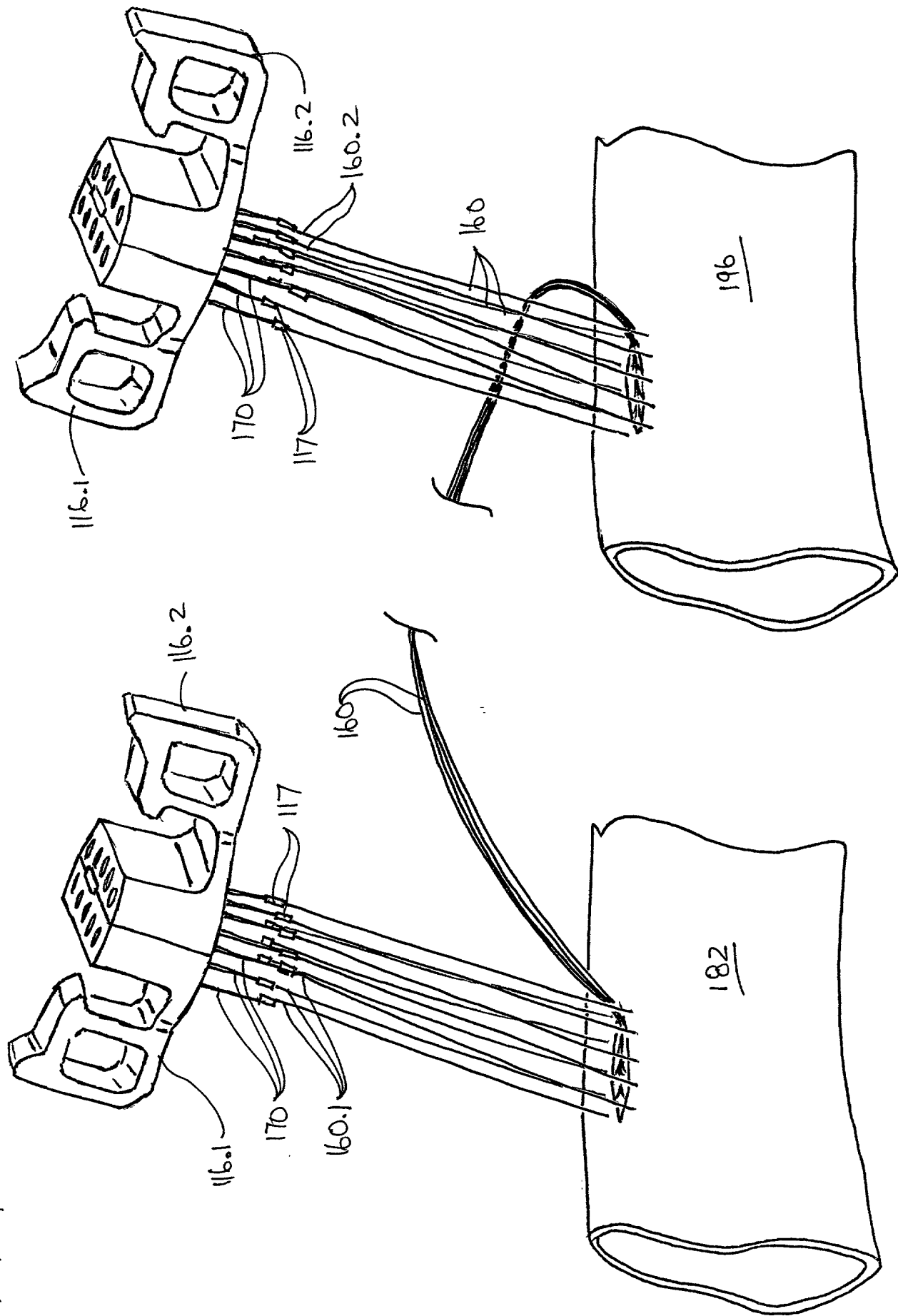
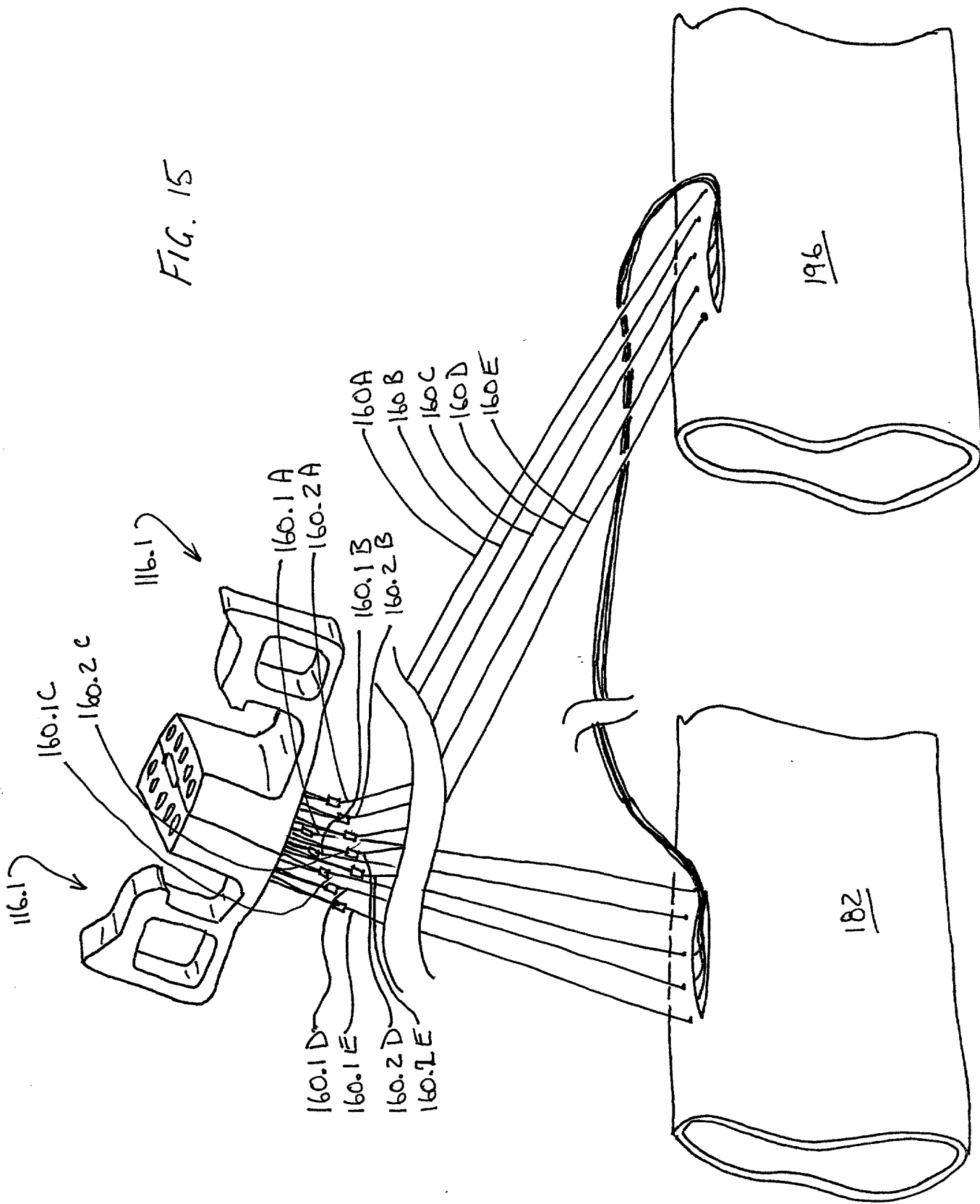


FIG. 13

FIG. 14





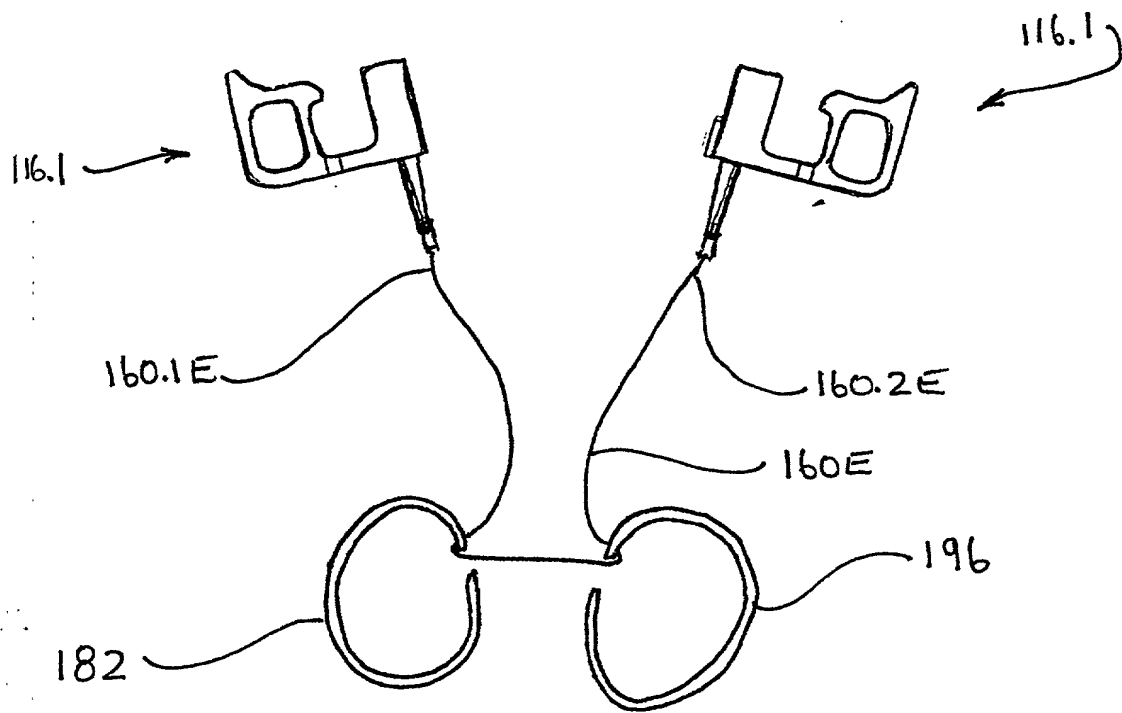


FIG 15A

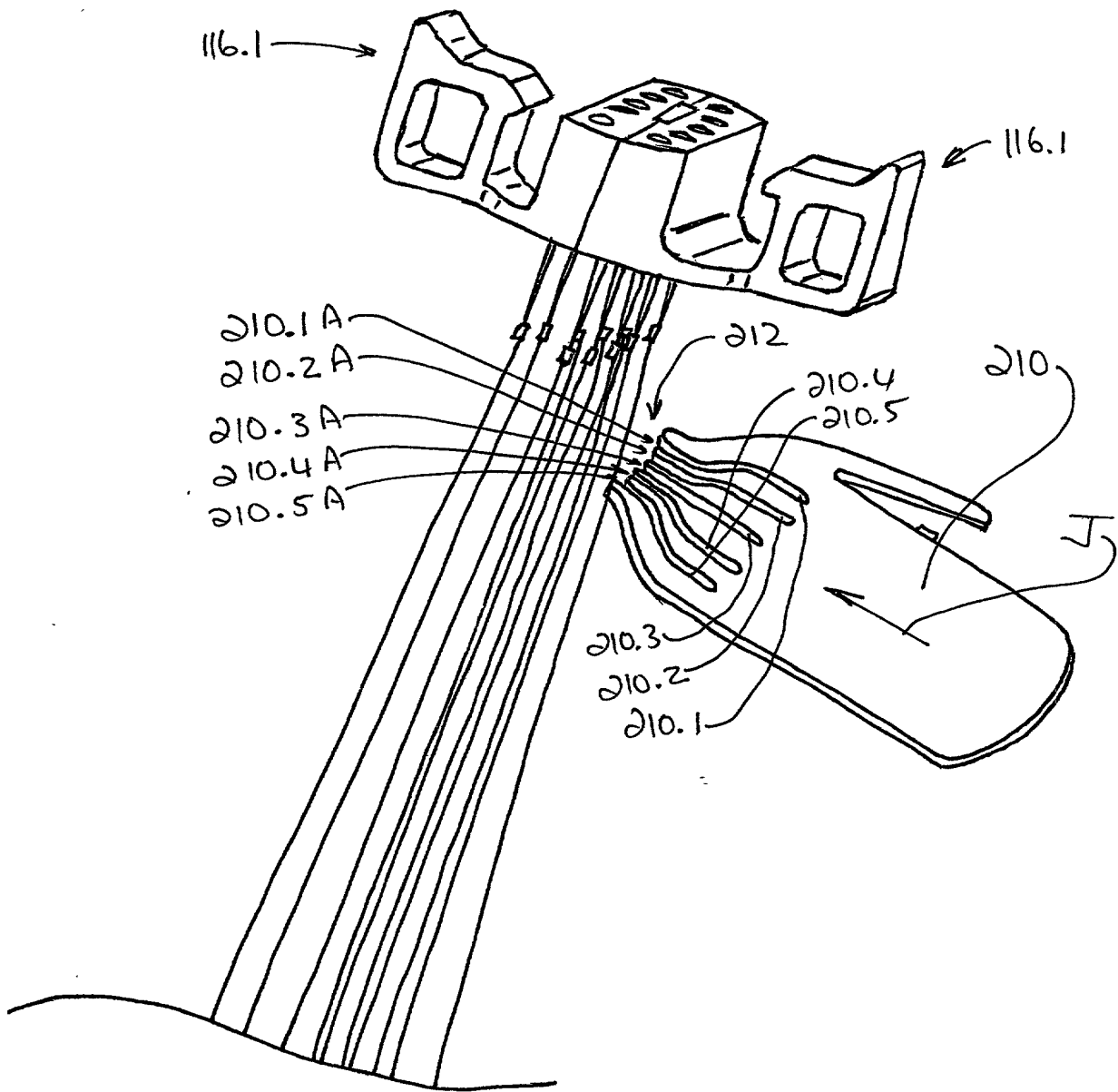


FIG. 16

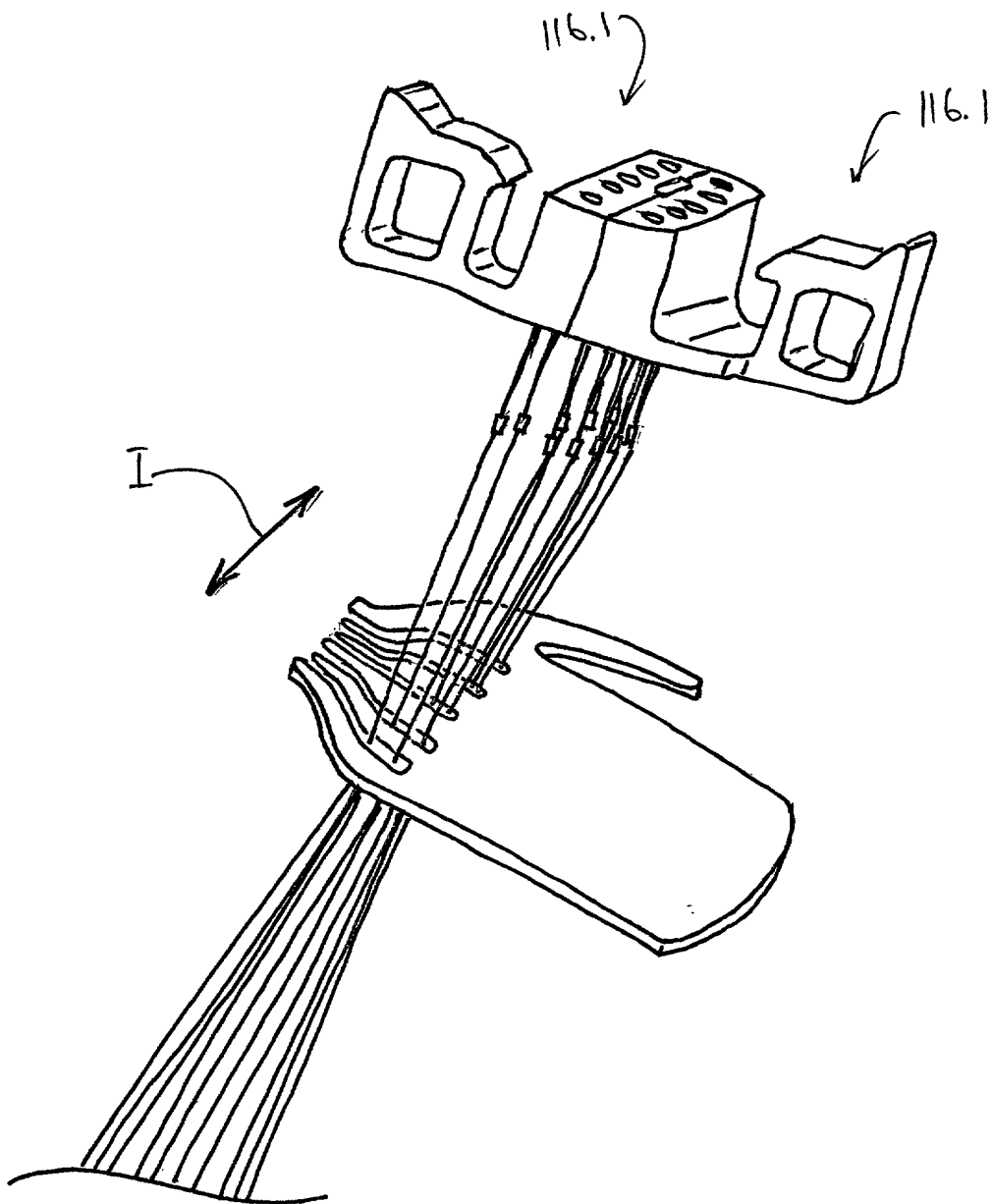


FIG. 17

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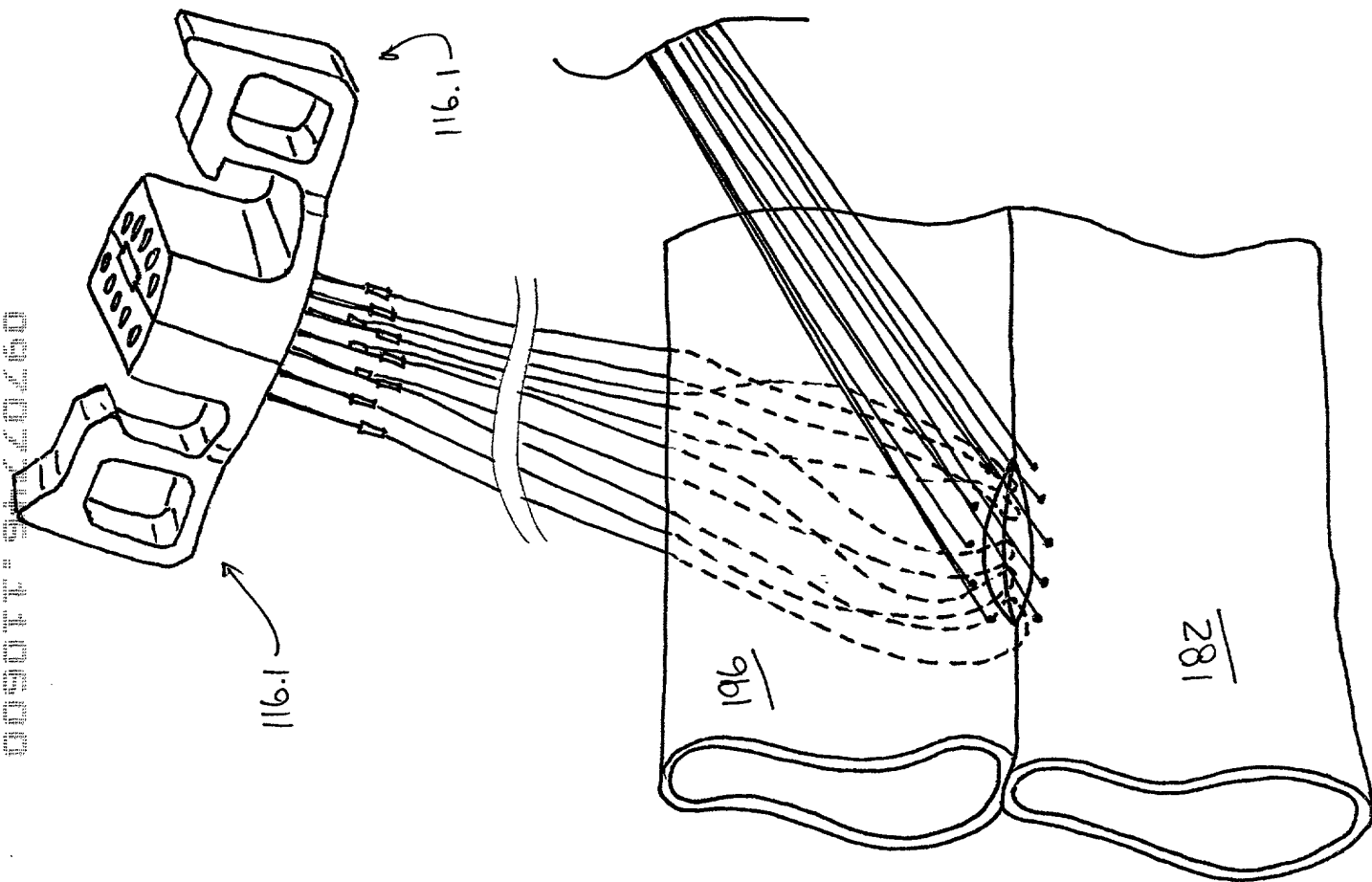
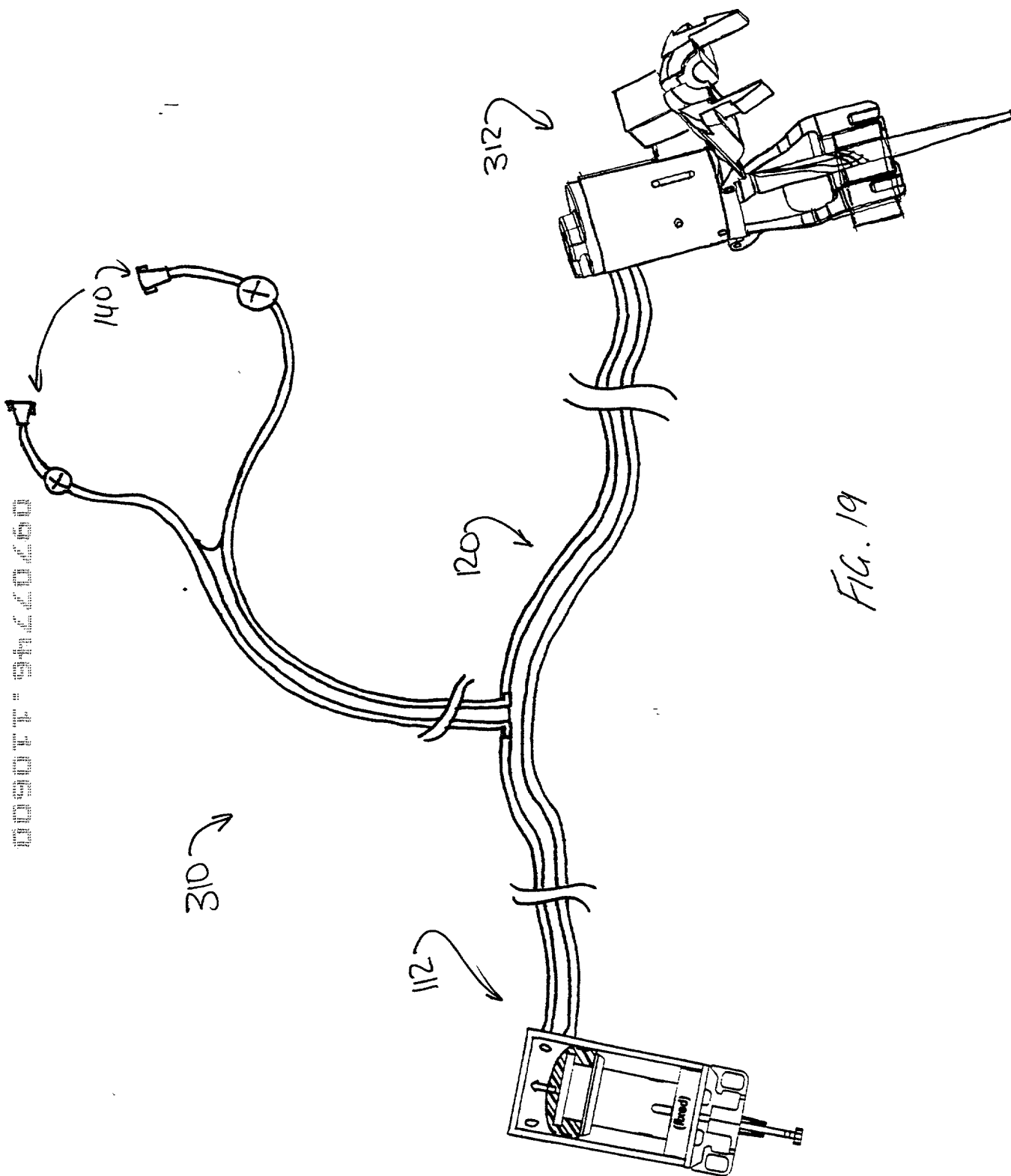


Fig. 18



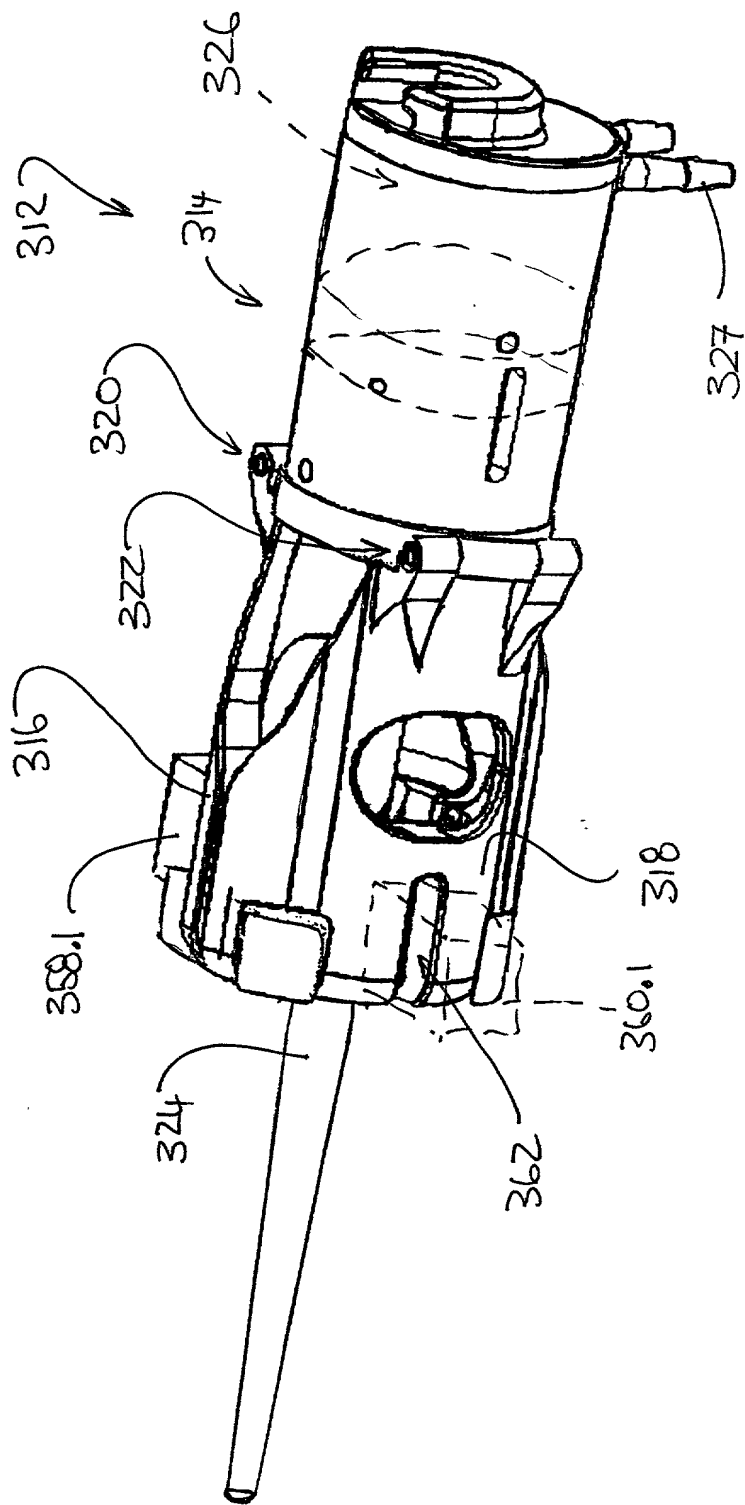
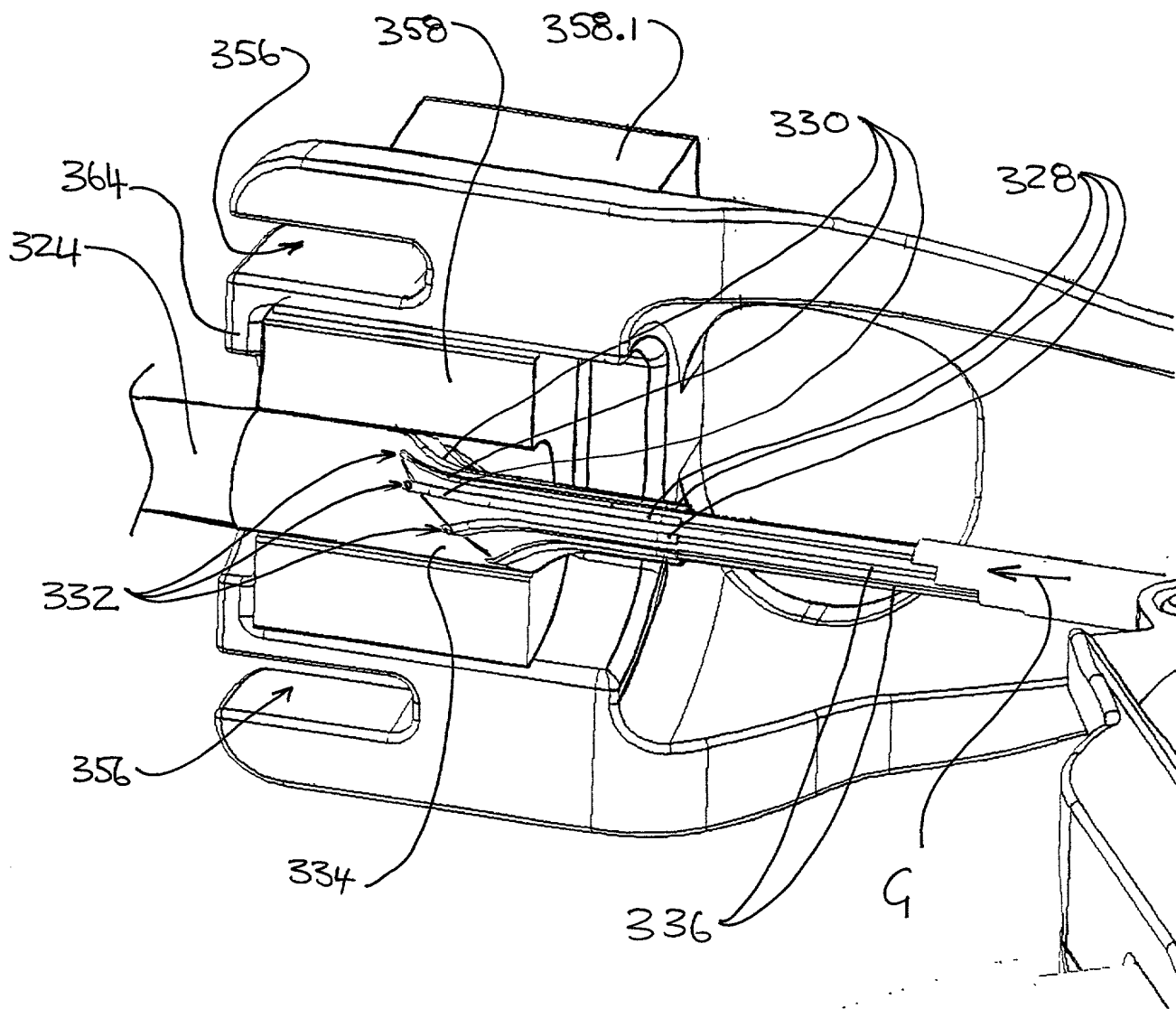


FIG. 20

FIG. 21



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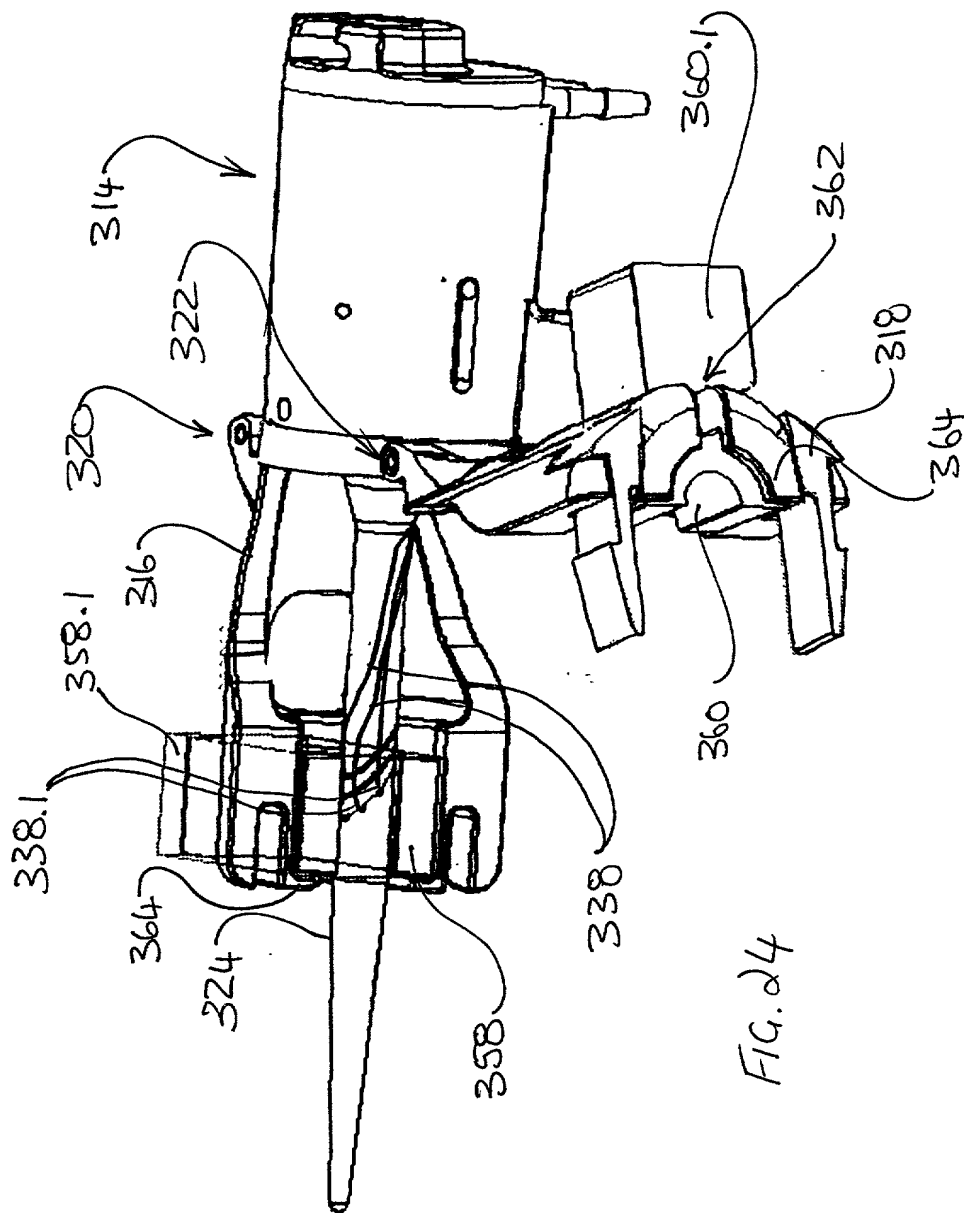
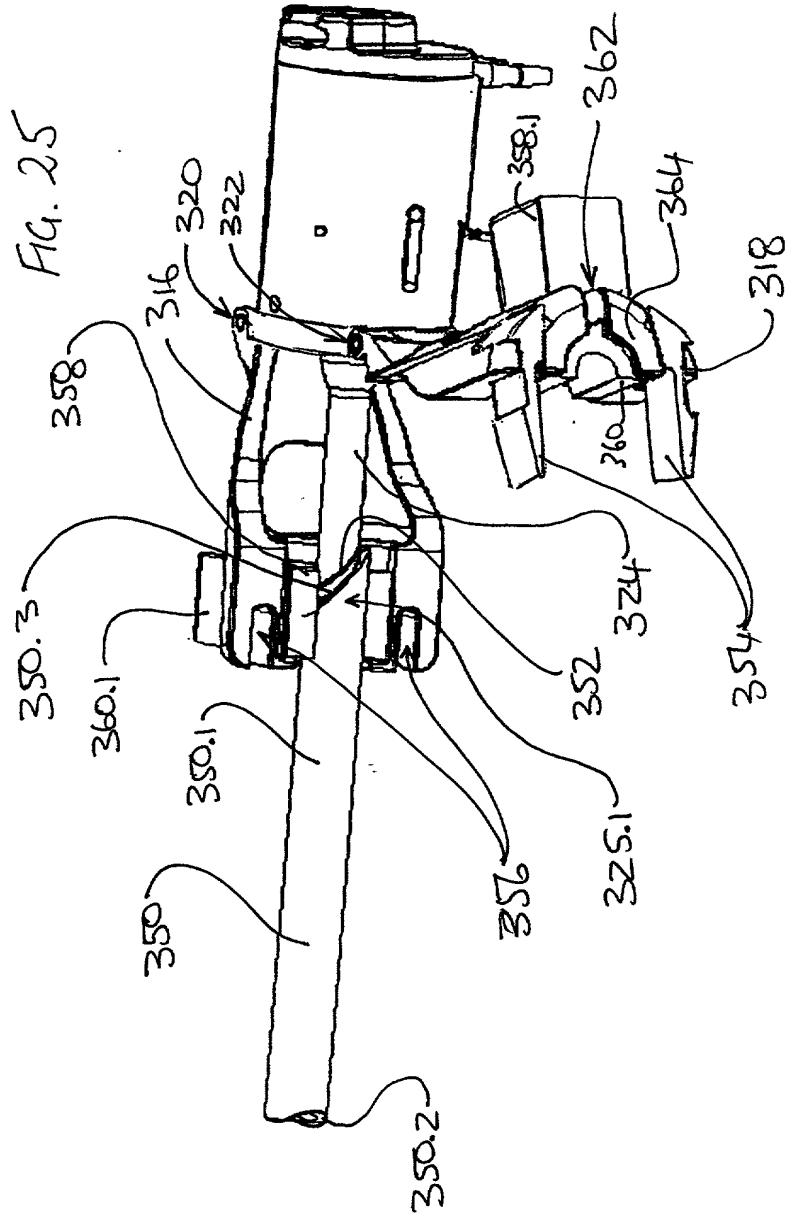
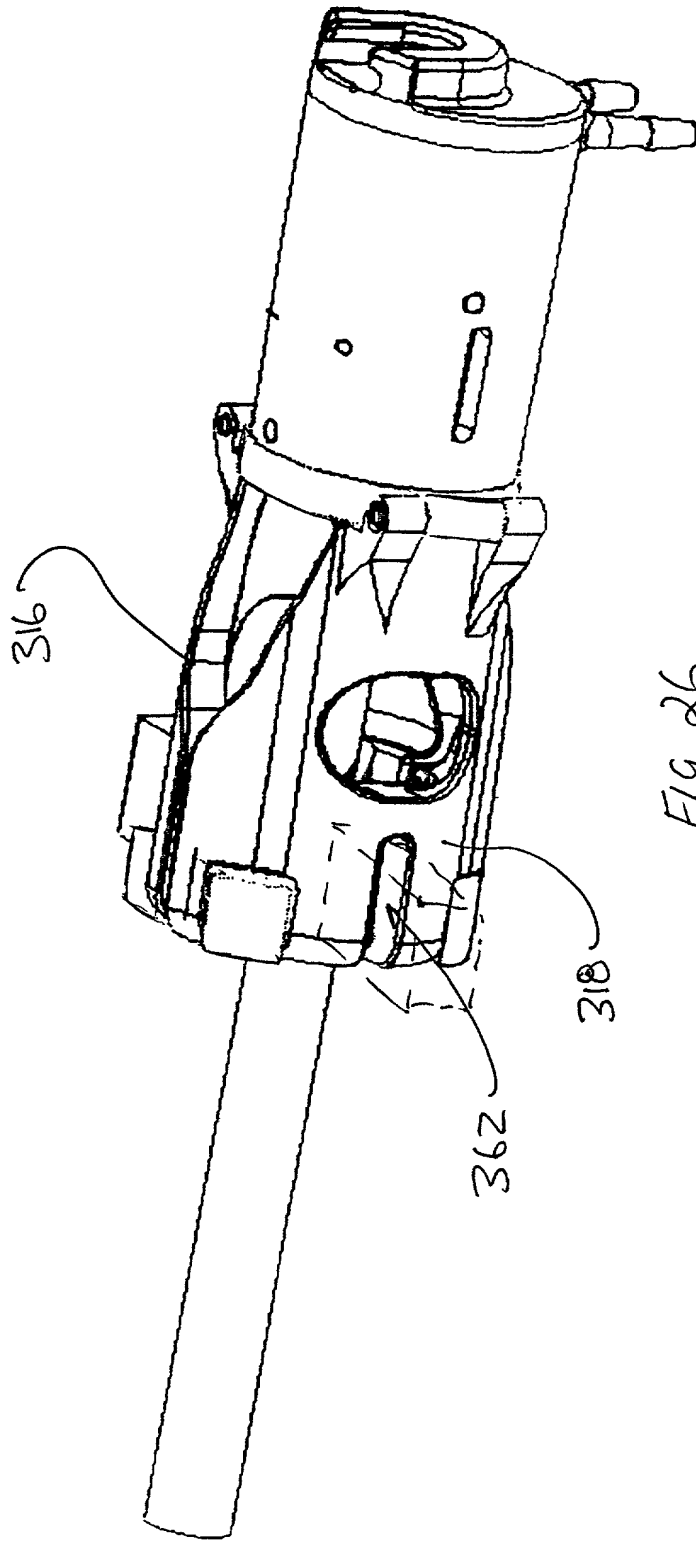


FIG. 24





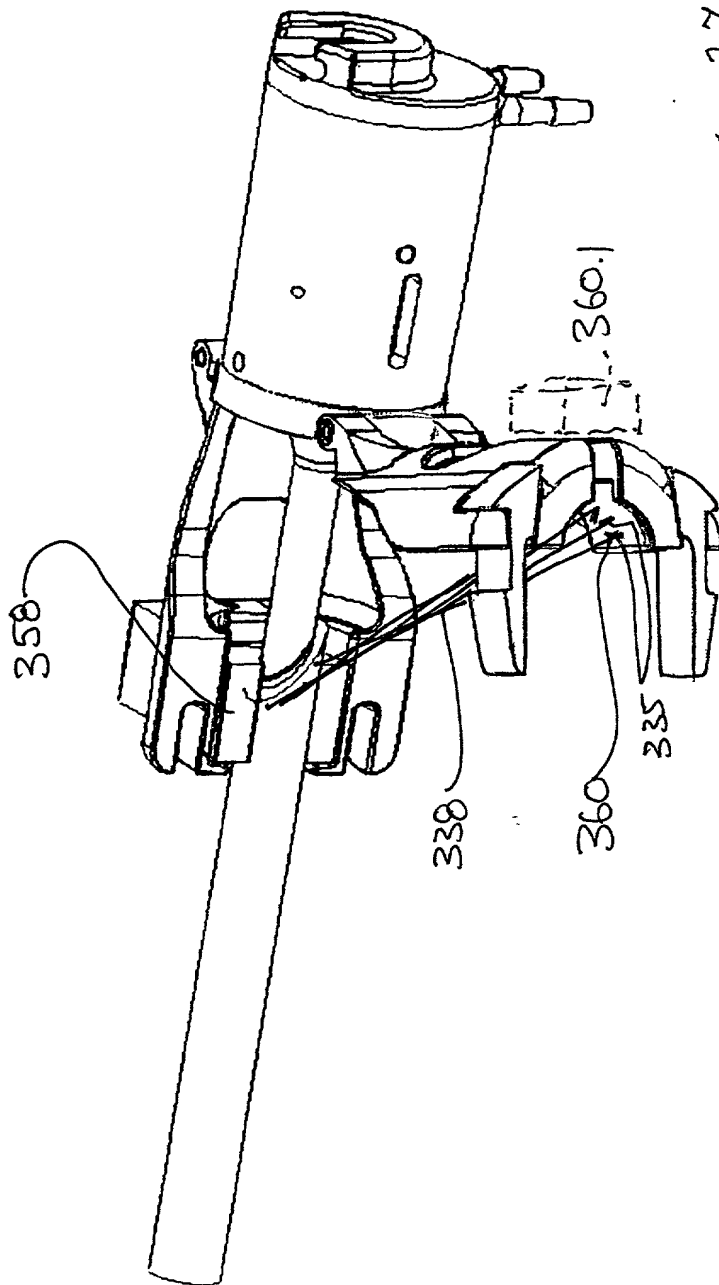


FIG. 27

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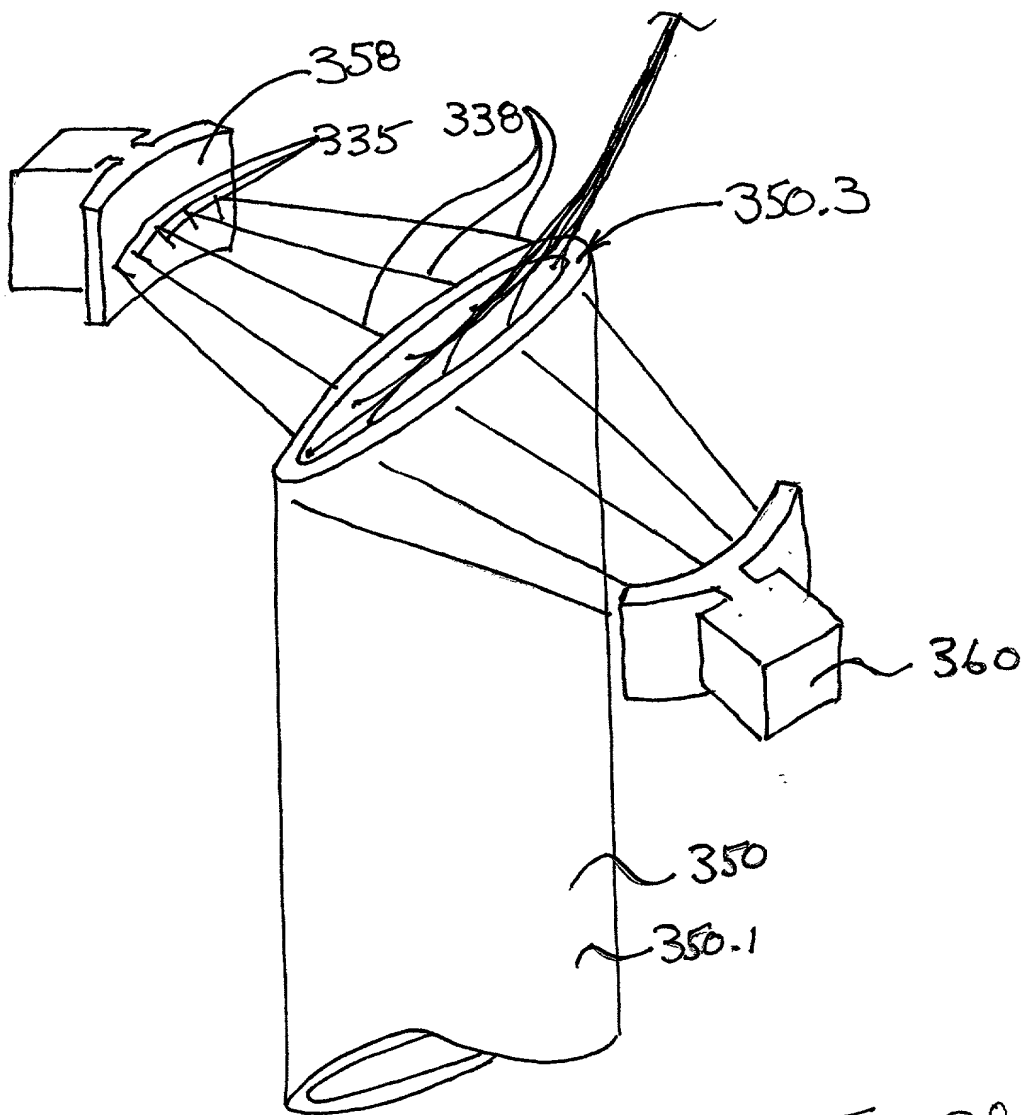


FIG. 28

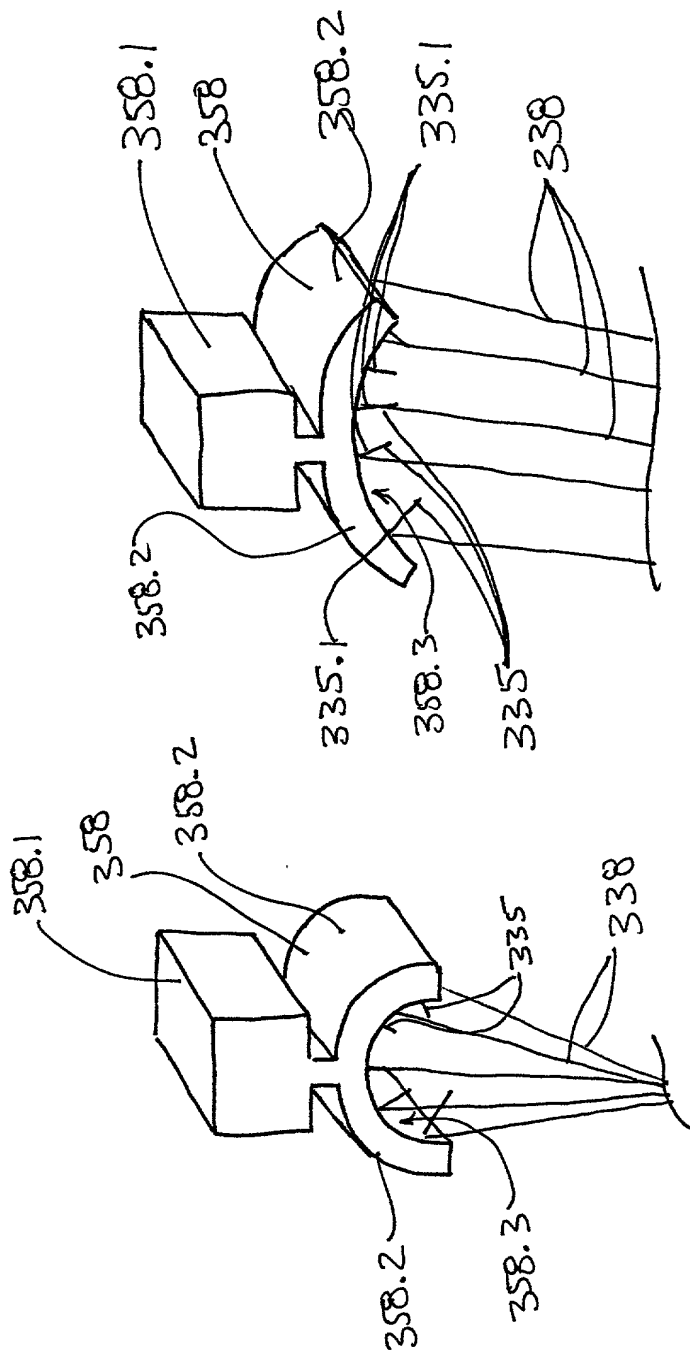


FIG. 28A

FIG. 28B

DECLARATION

As a below named inventor, I declare that:

My residence, post office address and citizenship are as stated below next to my name; I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **SYSTEMS, DEVICES AND METHODS FOR SUTURING PATIENT TISSUE** the specification of which X is attached hereto or was filed on as Application No. and was amended on (if applicable).

I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above. I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56. I claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Country	Application No.	Date of Filing	Priority Claimed Under 35 USC 119

Thereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

Application No.	Filing Date

I claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application No.	Date of Filing	Status

Full Name of Inventor 1:	Last Name: BURDULIS, JR.	First Name: ALBERT	Middle Name or Initial: G.	
Residence & Citizenship:	City:	State/Foreign Country: California	Country of Citizenship: United States	
Post Office Address:	Post Office Address:	City:	State/Country: California	Postal Code:
Full Name of Inventor 2:	Last Name: WHITIN	First Name: KATHERINE	Middle Name or Initial:	
Residence & Citizenship:	City: Redwood City	State/Foreign Country: California	Country of Citizenship: United States	
Post Office Address:	Post Office Address: 2607, Hastings Shore Ln.	City: Redwood City	State/Country: California	Postal Code: 94065

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature of Inventor 1	Signature of Inventor 2
<div>Albert G. Burdulis, Jr.</div>	<div>Katherine Whitin</div>
Date	Date

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